ID	CT.GOV Data Requirement		BRIDG Model Element		
	Data Item	Comment	Class	Attribute	Comment
1	Accepts on Healthy Volunteers?	Indicate if persons who have not had the condition(s) being studied or otherwise related conditions or symptoms, as specified in the eligibility requirements, may participate in the study. Select Yes/No.	InterventionalStudy	acceptsHealthyVolunteersIndicator	
2	Acronym	Definition: Acronym or initials used to identify this study, if applicable. Enter only the acronym. If supplied, the acronym is automatically displayed in parentheses following the brief title. Example: Brief Title: Women's Health Initiative Acronym: WHI Displayed on ClinicalTrials.gov as: Women's Health Initiative (WHI)	Study	acronym	
3	Allocation	Participant assignment to intervention group (at least one of the following required: Intervention Model, Masking, Allocation. All may be required as part of Study Design under PL 110-85, Section 801) - N/A: single arm study - Randomized Controlled Trial: participants are assigned to intervention groups by chance - Nonrandomized Trial: participants are expressly assigned to intervention groups through a nonrandom method, such as physician choice	InterventionalStudy	allocationCode	
4	Arm Description (note: above data element definition incorrect?) (aka Group/cohort Description)	Brief description of the arm. This element may not be necessary if the associated intervention descriptions contain sufficient information to describe the arm.	Arm	description	
5	Arm Label (aka Group/Cohort Label)	The short name used to identify the arm. Examples: - Metformin - Lifestyle counseling - Sugar pill	Arm	name	
6	Arm Type	Select one - Experimental - Active Comparator - Placebo Comparator - Sham Comparator - No intervention - Other	Arm	typeCode	

ID	CT.GOV Data Requirement		BRIDG Model Element		
	Data Item	Comment	Class	Attribute	Comment
7	Arms/Groups (intended to reflect the intervention assignment to the arm)	If arms or groups have been specified for the protocol, select the ones for which the intervention is to be administered. For interventional studies with arms specified, all arms must have at least one intervention (unless arm type is "No Intervention") and each intervention must be assigned to at least one arm. For observational studies with groups specified, each intervention (if any) must be assigned to at least one group.	Arm	typeCode	
8	Backup Central Contact: Degree	Degree	Person	name	
9	Backup Central Contact: Information (phone, e-mail)	Phone number of the Office phone of the facility contact person. Use the format 123-456-7890 within the United States and Canada. Otherwise, provide the country code. Ext: phone extension, if needed. Email: Electronic mail address of the facility contact person.	Person	telecomAddress	
10	Backup Central Contact: Name (first, middle int, last)	First Name, Middle Initial, Last Name	Person	name	
11	Backup Facility Contact: Degree	Degree	Person	name	
12	Backup Facility Contact: Information (phone, e-mail)	Phone number of the Office phone of the facility contact person. Use the format 123-456-7890 within the United States and Canada. Otherwise, provide the country code. Ext: phone extension, if needed. Email: Electronic mail address of the facility contact person.	Person	telecomAddress	
13	Backup Facility Contact: Name (first, middle int, last)	First Name, Middle Initial, Last Name	Person	name	
14	Biospecimen Description	Specify all types of biospecimens to be retained (e.g., whole blood, serum, white cells, urine, tissue).	Material	name	
15	Biospecimen Retention	- None Retained - no samples Retained - samples With DNA - samples Retained, With potential for extraction of DNA from at least one of the types of samples Retained (e.g., frozen tissue, whole blood) - samples Without DNA - samples Retained, With no potential for DNA extraction from any Retained samples (e.g., fixed tissue, plasma)	StudyAgent	functionCode	
16	Brief Summary (note: Trial Purpose & Objective on "other" worksheet)	Short description of the protocol intended for the lay public. Include a brief statement of the study hypothesis.	Study	purposeStatement	

ID	CT.GOV Data Requirement		BRIDG Model Element		
	Data Item	Comment	Class	Attribute	Comment
17	Brief Title	Definition: Protocol title intended for the lay public. Example: Safety Study of Recombinant Vaccinia Virus Vaccine to Treat Prostate Cancer	StudyProtocolDocument	publicTitle	
18	Central Contact	Email address, telephone number, or postal address of the contact who will respond to general queries, including information about current recruitment status.	Person	name	
19	Central Contact: Role (Primary or Backup)	Primary or Backup	StudyColleague	roleCode	
20	Citation	Bibliographic reference in NLM's MEDLINE format. Example: Barza M; Pavan PR; Doft BH; Wisniewski SR; Wilson LA; Han DP; Kelsey SF. Evaluation of microbiological diagnostic techniques in postoperative endophthalmitis in the Endophthalmitis Vitrectomy Study. Arch Ophthalmol 1997 Sep;115(9):1142-50	StudyReference	citationDescription	
21	Collaborators	Other organizations (if any) providing support, including funding, design, implementation, data analysis and reporting. The data provider is responsible for confirming all collaborators before listing them. Provide up to 10 full names of collaborating organizations.	Organization	name	
22	Collaborators	Person is not defined in CT.gov	Organization	name	
23	Collaborators includes funding sponsors	Funding Organization	Organization	name	
24	Collaborators includes funding sponsors	Funding Person	Organization	name	
25	CT.gov	Indicator of IND/IDE	RegulatoryApplication	typeCode	
26	CT.gov	Indicate if the protocol involves an Investigational New Drug Application (IND) or Investigational Device Exemption (IDE) under US Food and Drug Administration regulations (Will not be made public - for administrative purposes only.) The valid values are Yes or No.	RegulatoryApplication	typeCode	

ID	CT.GOV Data Requirement		BRIDG Model Element		
	Data Item	Comment	Class	Attribute	Comment
27	Data Monitoring Committee?	Indicate whether a data monitoring committee has been appointed for this study. The data monitoring committee (board) is a group of independent scientists who are appointed to monitor the safety and scientific integrity of a human research intervention, and to make recommendations to the sponsor regarding the stopping of the trial for efficacy, for harms or for futility. The composition of the committee is dependent upon the scientific skills and knowledge required for monitoring the particular study.	Organization	name	
28	Delayed Posting?	If this is a Section 801 applicable clinical trial, indicate whether this trial includes a device NOT previously approved or cleared by the US FDA for any use, as specified in US Public Law 110-85, Title VIII, Section 801. Select Yes/No. If "Yes" is selected, full posting of the trial information on ClinicalTrials.gov will be delayed until after the device has been approved or cleared. At that time, it is the registrant's responsibility to change this selection to "No" and release the record for full publication.	StudyProtocolDocument	publicDescription	
29	Detailed description	The reason for performing a trial in terms of the scientific questions to be answered by the analysis of data collected during the trial. NOTE: The primary objective is the main question to be answered and drives any statistical planning for the trial (e.g., calculation of the sample size to provide the appropriate power for statistical testing). Secondary objectives are goals of a trial that will provide further information on the use of the treatment.	StudyObjective	description	
30	Detailed Description	Extended description of the protocol, including more technical information (as compared to the Brief Summary) if desired. Do not include the entire protocol; do not duplicate information recorded in other data elements, such as eligibility criteria or outcome measures.	StudyProtocolDocument	publicDescription	

ID	CT.GOV Data Requirement		BRIDG Model Element		
	Data Item	Comment	Class	Attribute	Comment
31	Detailed Description (suggest changing "detailed description" on CT.gov sheet to "Brief summary")	A statement describing the overall rationale of the study. This field describes the contribution of this study to product development, i.e., what knowledge is being contributed from the conduct of this study. Note: This differs from StudyObjective describes what the study hopes to accomplish whereas the purposeStatement is the reason why the study is being conducted.	Study	purposeStatement	
32	Eligibility Criteria/Study population description	Summary criteria for participant selection. The preferred format includes lists of inclusion and exclusion criteria as shown below. Example: Inclusion Criteria: - Clinical diagnosis of Alzheimer's Disease - Must be able to swallow tablets Exclusion Criteria: - Insulin dependent diabetes - Thyroid disease	Study	populationDescription	
33	Enrollment (Target or Actual Number of Subjects)	Number of subjects in the trial. A "Type" menu is also included, with options Anticipated and Actual. For active studies, set Type to Anticipated and specify the expected enrollment, updating the number as needed over the course of the study. Upon study completion, change Type to Actual and update the enrollment if necessary.	Study	targetAccrualNumberRange	
34	Expanded Access Status	Indicate whether any non-protocol access is to be provided for the investigational drug or device. If so, an Expanded Access record should also be created for this IND/IDE. The valid values are Yes or No.	Study	plannedStudySubjectExperience	

ID	CT.GOV Data Requirement		BRIDG Model Element		
	Data Item	Comment	Class	Attribute	Comment
35	Expanded Access Status	Status indicating availability of an experimental drug or device outside any clinical trial protocol. This data element is only applicable for Expanded Access records (see Expanded Access under Study Type). Select one. - Available: expanded access is currently available for this treatment. - No longer available: expanded access was available for this treatment previously but is not currently available and will not be available in the future. - Temporarily not available: expanded access is not currently available for this treatment, but is expected to be available in the future. - Approved for marketing: this treatment has been approved for sale to the public.	Study	plannedStudySubjectExperience	
36	Facility Contact: Role (Primary or Backup)	Primary or Backup	StudyColleague	roleCode	
37	Facility Recruitment Status (using a code list)	Protocol accrual activity at a facility. Select one. - Not yet recruiting: participants are not yet being recruited - Recruiting: participants are currently being recruited - Enrolling by invitation: participants are being (or will be) selected from a predetermined population - Active, not recruiting: study is ongoing (i.e., patients are being treated or examined), but participants are not currently being recruited or enrolled - Completed: the study has concluded normally; participants are no longer being examined or treated (i.e., last patient's last visit has occurred) - Suspended: recruiting or enrolling participants has halted prematurely but potentially will resume - Terminated: recruiting or enrolling participants has halted prematurely and will not resume; participants are no longer being examined or treated - Withdrawn: study halted prematurely, prior to enrollment of first participant	StudySite	accrualStatusCode	

ID	CT.GOV Data Requirement		BRIDG Model Element		
	Data Item	Comment	Class	Attribute	Comment
38	FDA Regulated Intervention?	Indicate whether this trial includes an intervention subject to US Food and Drug Administration regulation under section 351 of the Public Health Service Act or any of the following sections of the Federal Food, Drug and Cosmetic Act: 505, 510(k), 515, 520(m), and 522. Select Yes/No.	Organization	name	
39	Gender	Physical gender of individuals who may participate in the protocol. Select one. - Both: both female and male participants are being studied - Female: only female participants are being studied - Male: only male participants are being studied	PlannedContingentOnRelationship	evaluableExpression	Proposed addition to BRIDG
40	Human Subjects Review Board Affiliation	Institutional Review Board Name, Affiliation and Contact Information	Organization	name	
41	Human Subjects Review Board Approval Number	Number assigned by the human subjects review board upon approval of the protocol. May be ommitted if status is anything other than approved. If the human subjects review board does not assign numbers, please enter the date of approval in mm/dd/yyyy format. (required only if status is "Submitted, approved")	Activity	identifier	
42	Human Subjects Review Board Approval Status	Human subjects review board approval status. Select one. - Request not yet submitted: review board approval is required but has not yet been requested - Submitted, pending: review board approval has been requested but not yet granted - Submitted, approved: review board approval has been requested and obtained - Submitted, exempt: review board has granted an exemption in response to the approval request - Submitted, denied: review board has denied the approval request - Submission not required: the study does not require human subjects review	StudyOverallStatus	statusCode	
43	Human Subjects Review Board Name, Affiliation and Contact	Institutional Review Board Name, Affiliation and Contact Information	Organization	name	
44	ID Source	The organization assigning the protocol identifier. NOTE: There may be multiple numbers (Nat'l number, coop group number). [PRG, eudraCT]	DocumentIdentifier	identifier	
45	ID Type	Identify kind of ID -- eg NIH Grant, Funding, Registry, Other	DocumentIdentifier	typeCode	

ID	CT.GOV Data Requirement		BRIDG Model Element		
	Data Item	Comment	Class	Attribute	Comment
46	IND/IDE Grantor	FDA center to which the IND or IDE was submitted, i.e., Center for Drug Evaluation and Research (CDER) or Center for Biologics Evaluation and Research (CBER) for INDs; Center for Devices and Radiological Health (CDRH) for IDEs. Select one. (Will not be made public - for administrative purposes only.)	RegulatoryAuthority	juridictionCode	
47	IND/IDE Number	Number assigned to an Investigational New Drug Application (IND) or Investigational Device Exemption (IDE). (Will not be made public - for administrative purposes only.) Examples: 22,333; BB1234	RegulatoryApplication	identifier	
48	Intervention Description	Comparator dosage/regimen info	DefinedSubstanceAdministration	doseRegimen	
49	Intervention Description	The route by which the product is administered.	DefinedSubstanceAdministration	routeOfAdministrationCode	
50	Intervention Description	Cover key details of the intervention. Must be sufficiently detailed to distinguish between arms of a study (e.g., comparison of different dosages of drug) and/or among similar interventions (e.g., comparison of multiple implantable cardiac defibrillators). For example, interventions involving drugs may include dosage form, dosage, frequency and duration	InterventionalStudy	interventionDescription	
51	Intervention Description	Amount of dose administered as part of the study regimen	DefinedSubstanceAdministration	doseRegimen	
52	Intervention Description	Method used to administer the study drug to the subject.	DefinedSubstanceAdministration	routeOfAdministrationCode	
53	Intervention Model	Clinical trial design developed to compare treatment groups in a clinical trial. NOTE: The configuration usually requires randomization to one or more treatment arms, each arm being allocated a different (or no) treatment. Examples include: Parallel Group Design, Crossover Design, Factorial Designs. [from ICH E9]	Study	designConfigurationCode	

ID	CT.GOV Data Requirement		BRIDG Model Element		
	Data Item	Comment	Class	Attribute	Comment
54	Intervention Name	For drugs use generic name; for other types of interventions provide a brief descriptive name. For investigational new drugs that do not yet have a generic name, a chemical name, company code or serial number may be used on a temporary basis. As soon as the generic name has been established, update the associated protocol records accordingly. For non-drug intervention types, provide an intervention name with sufficient detail so that it can be distinguished from other similar interventions	Product	nameCode	
55	Intervention Type	Select one per intervention - Drug (including placebo) - Device (including sham) - Biological/Vaccine - Procedure/Surgery - Radiation - Behavioral (e.g., Psychotherapy, Lifestyle Counseling) - Genetic (including gene transfer, stem cell and recombinant DNA) - Dietary Supplement (e.g., vitamins, minerals) - Other	Study	primaryPurposeCode	
56	Investigators (at the protocol location)	An investigator assigned the responsibility for the coordination of investigators at different centers participating in a multicenter trial. [ICH E6]	Person	name	
57	Investigators (at the protocol location)	A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator. [ICH] 21 CFR 50.3 expands on the ICH definition by stating that the investigator is the individual "under whose immediate direction the test article is administered or dispensed to, or used involving, a subject, or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team."	Person	name	
58	Investigators: Degree	Degree	Person	name	
59	Investigators: Name (first, middle int, last)	First Name, Middle Initial, Last Name	Person	name	
60	Investigators: Role (principle or sub investigator)	Primary or Sub Investigator	StudyColleague	roleCode	

ID	CT.GOV Data Requirement		BRIDG Model Element		
	Data Item	Comment	Class	Attribute	Comment
61	Keywords	Words or phrases that best describe the protocol. Keywords help users find studies in the database. Use NLM's Medical Subject Heading (MeSH) controlled vocabulary terms where appropriate. Be as specific and precise as possible. Avoid acronyms and abbreviations.	Document	keywordText	
62	Masking	Knowledge of intervention assignments (at least one of the following required: Intervention Model, Masking, Allocation. All may be required as part of Study Design under PL 110-85, Section 801) - Open: no masking is used. All involved know the identity of the intervention assignment. - Single Blind: one party, either the investigator or participant, is unaware of the intervention assignment; also called single-masked study. - Double Blind: two or more parties are unaware of the intervention assignment If Single Blind or Double Blind is selected, check the role(s) that are to be masked: Subject, Caregiver, Investigator or Outcomes Assessor.	InterventionalStudy	blindingSchemaCode	
63	Maximum Age	Maximum age of participants. Provide a number and a unit of time (years, months, weeks, days, hours or minutes). Select "N/A (No limit)" if no maximum age is indicated.	PlannedContingentOnRelationship	evaluableExpression	Proposed addition to BRIDG
64	MEDLINE Identifier	Unique PubMed Identifier (PMID) for the citation in MEDLINE. Example: PMID: 10987815	StudyReference	publicationIdentifier	
65	Minimum Age	Minimum age of participants. Provide a number and select a unit of time (years, months, weeks, days, hours or minutes). Select "N/A (No limit)" if no minimum age is indicated.	PlannedContingentOnRelationship	evaluableExpression	Proposed addition to BRIDG
66	Note: CTGOV has "Citatons" which are categorized by "Results" vs "Other" -- the citation words in the CT.gov elements suggest those are already "results". If you know it is a result than you don't need the flag else you need this flag	An indication that the published results citation related to the current study.	StudyReference	publicationIdentifier	
67	Number of Arms (aka "Number of Groups/cohorts")	Number of intervention groups (enter 1 for single-arm study).	Study	plannedStudySubjectExperience	

ID	CT.GOV Data Requirement		BRIDG Model Element		
	Data Item	Comment	Class	Attribute	Comment
68	Observational Time Perspective	Temporal relationship of observation period to time of subject enrollment. Select one. - Prospective: look forward using periodic observations collected predominantly following subject enrollment - Retrospective: look back using observations collected predominantly prior to subject selection and enrollment - Cross-sectional: observations or measurements made at a single point in time, usually at subject enrollment - Other - explain in Detailed Description	ObservationalStudy	timePerspectiveCode	
69	Official Title	Definition: Official name of the protocol provided by the study principal investigator or sponsor. Example: Phase 1 Study of Recombinant Vaccinia Virus That Expresses Prostate Specific Antigen in Metastatic Adenocarcinoma of the Prostate	Document	officialTitle	
70	Organization's Unique Protocol ID Secondary IDs	Unique identification assigned to the protocol by the sponsoring organization, usually an accession number or a variation of a grant number. Multiple studies conducted under the same grant must each have a unique number. Examples: ABT-1233-RV Merck-023 ACTG 021	DocumentIdentifier	identifier	
71	Organization's Unique Protocol ID Secondary IDs	Protocol Identifying Number: Any of one or more unique codes that refers to a specific protocol. NOTE: There may be multiple numbers (Nat'l number, coop group number). [PRG; eudraCT] Other identifying numbers and issuing authorities besides the Primary Registry, if any. Include the sponsor name and sponsor-issued trial number (e.g., protocol number) if available. Also include other trial registries that have issued an identifying number to this trial. There is no limit on the number of Secondary identifying numbers that can be provided. (WHO)	DocumentIdentifier	identifier	

ID	CT.GOV Data Requirement		BRIDG Model Element		
	Data Item	Comment	Class	Attribute	Comment
72	Other Names	List other names used to identify the intervention, past or present (e.g., brand name for a drug). These names will be used to improve search results in ClinicalTrials.gov.	Product	nameCode	
73	Overall Recruitment Status	StudyRecruitmentStatus: Status of finding and enrolling appropriate subjects (those selected on the basis of the protocol's inclusion and exclusion criteria) into a clinical study. StudyOverallStatus: Describes the comprehensive state of the study	StudyRecruitmentStatus	statusCode	
74	Overall Recruitment Status	Overall accrual activity for the protocol. Select one. Not yet recruiting: participants are not yet being recruited Recruiting: participants are currently being recruited Enrolling by invitation: participants are being (or will be) selected from a predetermined population Active, not recruiting: study is ongoing (i.e., patients are being treated or examined), but participants are not currently being recruited or enrolled Completed: the study has concluded normally; participants are no longer being examined or treated (i.e., last patient's last visit has occurred) Suspended: recruiting or enrolling participants has halted prematurely but potentially will resume Terminated: recruiting or enrolling participants has halted prematurely and will not resume; participants are no longer being examined or treated Withdrawn: study halted prematurely, prior to enrollment of first participant	StudyOverallStatus	statusCode	
75	Overall Study Officials	A person identified when the study is approved as the person responsible for the overall conduct of the clinical trial.	Person	name	
76	Overall Study Officials	Person(s) responsible for the overall scientific leadership of the protocol, including study principal. First Name, Middle Initial, Last Name investigator.	Person	name	
77	Overall Study Officials	Position or function of the official. Study Chair/Study Director/Study Principal Investigator	Person	name	
78	Overall Study Officials: Degree	Degree	Person	name	

ID	CT.GOV Data Requirement		BRIDG Model Element		
	Data Item	Comment	Class	Attribute	Comment
79	Overall Study Officials: Organizational Affiliation	Full name of the official's organization. If none, specify Unaffiliated. Organization Affiliation	Organization	name	
80	Oversight Authorities	The name of each national or international health organization with authority over the protocol. Use the following format for each authority: country: organization name Examples: United States: Institutional Review Board United States: Food and Drug Administration Germany: Federal Institute for Drugs and Medical Devices Australia: Therapeutic Goods Administration	Organization	name	
81	Oversight Authorities	The name of each national or international health organization with authority over the protocol.	Organization	name	
82	Primary Central Contact: Degree	Degree	Person	name	
83	Primary Central Contact: Information (phone, e-mail)	Phone number of the Office phone of the facility contact person. Use the format 123-456-7890 within the United States and Canada. Otherwise, provide the country code. Ext: phone extension, if needed. Email: Electronic mail address of the facility contact person.	Person	telecomAddress	
84	Primary Central Contact: Name (first, middle int, last)	Person providing centralized, coordinated recruitment information for the entire study. First Name, Middle Initial, Last Name	Person	name	
85	Primary Completion Date	As specified in US Public Law 110-85, Title VIII, Section 801, with respect to an applicable clinical trial, the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the prespecified protocol or was terminated.	StudyOverallStatus	statusDate	
86	Primary Completion Date Type	A "Type" menu is also included, with options Anticipated and Actual. For active studies, set Type to Anticipated and specify the expected completion date, updating the date as needed over the course of the study. Upon study completion, change Type to Actual and update the date if necessary.	StudyOverallStatus	anticipatedIndicator	

ID	CT.GOV Data Requirement		BRIDG Model Element		
	Data Item	Comment	Class	Attribute	Comment
87	Primary Completion Date	As specified in US Public Law 110-85, Title VIII, Section 801, with respect to an applicable clinical trial, the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the prespecified protocol or was terminated. A "Type" menu is also included, with options Anticipated and Actual. For active studies, set Type to Anticipated and specify the expected completion date, updating the date as needed over the course of the study. Upon study completion, change Type to Actual and update the date if	StudyOverallStatus	anticipatedIndicator	
88	Primary Facility Contact: Degree	Degree	Person	name	
89	Primary Facility Contact: Information (phone, e-mail)	Phone number of the Office phone of the facility contact person. Use the format 123-456-7890 within the United States and Canada. Otherwise, provide the country code. Ext: phone extension, if needed. Email: Electronic mail address of the facility contact person.	Person	telecomAddress	
90	Primary Facility Contact: Name (first, middle int, last)	First Name, Middle Initial, Last Name	Person	name	

ID	CT.GOV Data Requirement		BRIDG Model Element		
	Data Item	Comment	Class	Attribute	Comment
91	Primary Purpose (code list)	Reason for the protocol - Treatment: protocol designed to evaluate one or more interventions for treating a disease, syndrome or condition - Prevention: protocol designed to assess one or more interventions aimed at preventing the development of a specific disease or health condition - Diagnostic: protocol designed to evaluate one or more interventions aimed at identifying a disease or health condition - Supportive Care: protocol designed to evaluate one or more interventions where the primary intent is to maximize comfort, minimize side effects or mitigate against a decline in the subject's health or function. In general, supportive care interventions are not intended to cure a disease. - Screening: protocol designed to assess or examine methods of identifying a condition (or risk factors for a condition) in people who are not yet known to have the condition (or risk factor). - Health Services Research: protocol designed to evaluate the delivery, processes, management,	Study	primaryPurposeCode	
92	Protocol Location.Facility	Name: Full name of the organization where the protocol is being conducted	Organization	name	
93	Protocol Location: Partial Address (Facility City, State, Postal Code, Country)	Partial Address of Facility Location: City, State/Province, Postal Code, Country	StudySiteContact	postalAddress	
94	Record Verification Date	Date the protocol information was last verified. Verification date is shown along with organization name on ClinicalTrials.gov to indicate to the public whether the information is being kept current, particularly recruiting status and contact information. Update verification date when reviewing the record for accuracy and completeness, even if no other changes are made	StudyOverallStatus	statusDate	
95	References	Citations to publications related to the protocol: background and/or results. Provide either the unique PubMed Identifier (PMID) of an article or enter the full bibliographic citation.	StudyReference	publicationName	
96	Responsible Party Email	provide telephone number and/or email address [required for internal administrative use only; not revealed to public]	Person	telecomAddress	

ID	CT.GOV Data Requirement		BRIDG Model Element		
	Data Item	Comment	Class	Attribute	Comment
97	Responsible Party Name	Name/Official Title - for either the principal investigator or sponsor contact. As defined in US Public Law 110-85, Title VIII, Section 801, the term "responsible party", with respect to a clinical trial, means the sponsor of the clinical trial (as defined in 21 CFR 50.3) or the principal investigator of such clinical trial if so designated by a sponsor, grantee, contractor, or awardee, so long as the principal investigator is responsible for conducting the trial, has access to and control over the data from the clinical trial, has the right to publish the results of the trial, and has the ability to meet all of the requirements for the submission of clinical trial information.	Person	name	
98	Responsible Party Organization	the sponsor or the principal investigator's organizational affiliation	Organization	name	
99	Responsible Party Telephone	provide telephone number and/or email address [required for internal administrative use only; not revealed to public]	Person	telecomAddress	
100	Responsible Party Title	Name/Official Title - for either the principal investigator or sponsor contact. As defined in US Public Law 110-85, Title VIII, Section 801, the term "responsible party", with respect to a clinical trial, means the sponsor of the clinical trial (as defined in 21 CFR 50.3) or the principal investigator of such clinical trial if so designated by a sponsor, grantee, contractor, or awardee, so long as the principal investigator is responsible for conducting the trial, has access to and control over the data from the clinical trial, has the right to publish the results of the trial, and has the ability to meet all of the requirements for the submission of clinical trial information.	Person	name	
101	Results Reference?	Indicate if the reference provided reports on results from this clinical research study.	StudyReference	publicationIdentifier	
102	Safety Issue	An indication that the outcome measure for the study is safety related.	StudyOutcomeMeasure	typeCode	

ID	CT.GOV Data Requirement		BRIDG Model Element		
	Data Item	Comment	Class	Attribute	Comment
103	Sampling Method	For observational studies only, select one and explain in Detailed Description. - Probability Sample: exclusively random process to guarantee that each participant or population has specified chance of selection, such as simple random sampling, systematic sampling, stratified random sampling, cluster sampling, and consecutive patient sampling - Non-Probability Sample: any of a variety of other sampling processes, such as convenience sampling or invitation to volunteer	ObservationalStudy	samplingMethodCode	
104	Secondary IDs	Other identification numbers assigned to the protocol, including unique identifiers from other registries and NIH grant numbers, if applicable. Provide up to 5 Secondary ID Numbers, one per line. Examples: ISRCTN12345678 NCI-793-0115D R01-123456-1	DocumentIdentifier	identifier	
105	Section 801?	If this trial includes an FDA regulated intervention, indicate whether this is an "applicable clinical trial" as defined in US Public Law 110-85, Title VIII, Section 801. Briefly, applicable drug trials include controlled clinical investigations, other than Phase I investigations, of a drug or biologic subject to US FDA regulation. Applicable device clinical trials are controlled trials with health outcomes of devices subject to FDA regulation, other than small feasibility studies, and pediatric postmarket surveillance. Select Yes/No.	StudyProtocolDocument	publicDescription	
106	Sponsor	Name of primary organization that oversees implementation of study and is responsible for data analysis. For applicable clinical trials, sponsor is defined in 21 CFR 50.3. Examples: National Institute of Allergy and Infectious Diseases, Bristol-Myers Squibb	Organization	name	

ID	CT.GOV Data Requirement		BRIDG Model Element		
	Data Item	Comment	Class	Attribute	Comment
107	Sponsor	The individual, organization, group or other legal entity which takes responsibility for initiating, managing and/or financing a study. The Primary Sponsor is responsible for ensuring that the ensuring that the trial is properly registered. The Primary Sponsor may or may not be the main funder.	Organization	name	
108	Study Classification	Type of primary outcome or endpoint that the protocol is designed to evaluate. Select one. - N/A: not applicable - Safety: show if the drug is safe under conditions of proposed use - Efficacy: measure of an intervention's influence on a disease or health condition - Safety/Efficacy - Bio-equivalence: scientific basis for comparing generic and brand name drugs - Bio-availability: rate and extent to which a drug is absorbed or otherwise available to the treatment site in the body - Pharmacokinetics: the action of a drug in the body over a period of time including the process of absorption, distribution and localization in tissue, biotransformation, and excretion of the compound - Pharmacodynamics: action of drugs in living systems - Pharmacokinetics/dynamics	StudyOutcomeMeasure	typeCode	
109	Study Completion Date	Final date on which data was (or is expected to be) collected. Use the Type menu (Anticipated/Actual) as described above.	StudyOverallStatus	statusDate	
110	Study Design-Intervention Model	Plan for the precise procedure to be followed in a clinical trial, including planned and actual timing of events, choice of control group, method of allocating treatments, blinding methods; assigns a subject to pass through one or more epochs in the course of a trial. Specific design elements, e.g., crossover, parallel; dose-escalation [Modified from Pocock, Clinical Trials: A Practical Approach] See Trial Design Model. See also, arm, epoch, and visit.	Study	designConfigurationCode	
111	Study Design-Primary and Secondary Outcome Measures	Measure	StudyOutcomeMeasure	name	
112	Study Design-Primary and Secondary Outcome Measures	Primary or Secondary?	StudyOutcomeMeasure	name	
113	Study Design-Primary and Secondary Outcome Measures	Time Frame	StudyOutcomeMeasure	name	

ID	CT.GOV Data Requirement		BRIDG Model Element		
	Data Item	Comment	Class	Attribute	Comment
114	Study Design-Primary and Secondary Outcome Measures: Primary or Secondary??	Primary or Secondary?	StudyOutcomeMeasure	primaryIndicator	
115	Study Phase	Phase of investigation, as defined by the US FDA for trials involving investigational new drugs. (N/A, Phase 0, Phase 1, Phase 1/Phase2, Phase 2, Phase 2/Phase 3, Phase 3, Phase 4)	Study	phaseCode	
116	Study Population Description (applies to Observational)	For observational studies only, a description of the population from which the groups or cohorts will be selected (e.g., primary care clinic, community sample, residents of a certain town).	Study	populationDescription	
117	Study Start Date	Date that enrollment to the protocol begins.	StudyOverallStatus	statusDate	
118	Study Type	Definition: Nature of the investigation. Select one. Interventional: studies in human beings in which individuals are assigned by an investigator based on a protocol to receive specific interventions. Subjects may receive diagnostic, therapeutic or other types of interventions. The assignment of the intervention may or may not be random. The individuals are then followed and biomedical and/or health outcomes are assessed. Observational: studies in human beings in which biomedical and/or health outcomes are assessed in pre-defined groups of individuals. Subjects in the study may receive diagnostic, therapeutic, or other interventions, but the investigator does not assign specific interventions to the subjects of the study. Expanded Access: records describing the procedure for obtaining an experimental drug or device for patients who are not adequately treated by existing therapy, who do not meet the eligibility criteria for enrollment, or who are otherwise unable to participate in a controlled clinical	Study	~ derived based on specialization type	
119	Time Perspective (Observational Studies only, and the fit to the PRG definition isn't perfect)	A code specifying the temporal relationship of the control to the study intervention. For example, concurrent, historical, pre/post (patient owned control).	InterventionalStudy	controlConcurrencyTypeCode	

ID	CT.GOV Data Requirement		BRIDG Model Element		
	Data Item	Comment	Class	Attribute	Comment
120	URL	A Web site directly relevant to the protocol may be entered, if desired. Do not include sites whose primary goal is to advertise or sell commercial products or services. Complete URL, including http:// Example: http://www.alzheimers.org/	StudyReference	universalResourceLocator	
121	URL Description	Title or brief description of the linked page. If the page being linked is the protocol's home page on the sponsor's Web site, include the words "Click here for more information about this study:" and provide the name of the protocol. Examples: Click here for more information about this study: Clinical Trial of Eye Prophylaxis in the Newborn The Alzheimer's Disease Education and Referral (ADEAR) Center is a service of the National Institute on Aging	StudyReference	universalResourceLocator	
122	Why Study Stopped? Intended to represent the brief description (note: overall recruitment status would indicate terminated, w/d, suspended)	For suspended, terminated or withdrawn studies, provide a brief explanation of why the study has been halted or terminated. If desired, use brief summary or detailed description to provide additional information.	StudyOverallStatus	studyStoppedReasonCode	

ID	WHO.CTR Data Requirements		BRIDG Model Element		
	Data Item	Comment	Class	Attribute	Comment
1	Acronym	Definition: Acronym or initials used to identify this study, if applicable. Enter only the acronym. If supplied, the acronym is automatically displayed in parentheses following the brief title. Example: Brief Title: Women's Health Initiative Acronym: WHI Displayed on ClinicalTrials.gov as: Women's Health Initiative (WHI)	Study	acronym	
2	Allocation	Participant assignment to intervention group (at least one of the following required: Intervention Model, Masking, Allocation. All may be required as part of Study Design under PL 110-85, Section 801) - N/A: single arm study - Randomized Controlled Trial: participants are assigned to intervention groups by chance - Nonrandomized Trial: participants are expressly assigned to intervention groups through a nonrandom method, such as physician choice	InterventionalStudy	allocationCode	
3	Contact for Public Queries (WHO CTR item 7)	Email address, telephone number, or postal address of the contact who will respond to general queries, including information about current recruitment status.	Person	name	
4	Contact for Scientific Queries (WHO CTR item 8)	Person(s) responsible for the overall scientific leadership of the protocol, including study principal. First Name, Middle Initial, Last Name investigator.	Person	name	
5	Contact for Scientific Queries (WHO CTR item 8)	Position or function of the official. Study Chair/Study Director/Study Principal Investigator	Person	name	
6	Countries of Recruitment (WHO CTR item 11)	The countries from which participants will be, are intended to be, or have been recruited.	Study	participatingCountryCode	
7	Date of First Enrollment (WHO CTR item 16)	Date that enrollment to the protocol begins.	StudyOverallStatus	statusDate	

ID	WHO.CTR Data Requirements		BRIDG Model Element		
	Data Item	Comment	Class	Attribute	Comment
8	Health Condition(s) or Problem(s) Studied (WHO CTR item 12)	Primary health condition(s) or problem(s) studied (e.g., depression, breast cancer, medication error). If the study is conducted in healthy human volunteers belonging to the target population of the intervention (e.g. preventive or screening interventions), enter the particular health condition(s) or problem(s) being prevented. If the study is conducted in healthy human volunteers not belonging to the target population (e.g., a preliminary safety study), an appropriate keyword will be defined for users to select.	Study	diseaseCode	
9	Health Condition(s) or Problem(s) Studied (WHO CTR item 12)	Summary criteria for participant selection. The preferred format includes lists of inclusion and exclusion criteria as shown below. Example: Inclusion Criteria: - Clinical diagnosis of Alzheimer's Disease - Must be able to swallow tablets Exclusion Criteria: - Insulin dependent diabetes - Thyroid disease	Study	populationDescription	
10	inclusion/exclusion criteria	Maximum age of participants. Provide a number and a unit of time (years, months, weeks, days, hours or minutes). Select "N/A (No limit)" if no maximum age is indicated.	PlannedContingentOnRelationship	evaluableExpression	Proposed addition to BRIDG
11	inclusion/exclusion criteria	Minimum age of participants. Provide a number and select a unit of time (years, months, weeks, days, hours or minutes). Select "N/A (No limit)" if no minimum age is indicated.	PlannedContingentOnRelationship	evaluableExpression	Proposed addition to BRIDG
12	inclusion/exclusion criteria	Physical gender of individuals who may participate in the protocol. Select one. - Both: both female and male participants are being studied - Female: only female participants are being studied - Male: only male participants are being studied	PlannedContingentOnRelationship	evaluableExpression	Proposed addition to BRIDG
13	Intervention	Amount of dose administered as part of the study regimen	DefinedSubstanceAdministration	doseRegimen	
14	Intervention	Method used to administer the study drug to the subject.	DefinedSubstanceAdministration	routeOfAdministrationCode	

ID	WHO.CTR Data Requirements		BRIDG Model Element		
	Data Item	Comment	Class	Attribute	Comment
15	Intervention	For drugs use generic name; for other types of interventions provide a brief descriptive name. For investigational new drugs that do not yet have a generic name, a chemical name, company code or serial number may be used on a temporary basis. As soon as the generic name has been established, update the associated protocol records accordingly. For non-drug intervention types, provide an intervention name with sufficient detail so that it can be distinguished from other similar interventions.	Product	nameCode	
16	Intervention(s)	Cover key details of the intervention. Must be sufficiently detailed to distinguish between arms of a study (e.g., comparison of different dosages of drug) and/or among similar interventions (e.g., comparison of multiple implantable cardiac defibrillators). For example, interventions involving drugs may include dosage form, dosage, frequency and duration.	InterventionalStudy	interventionDescription	
17	Intervention(s) Includes control interventions. For each intervention, describe other intervention details as applicable (dose, duration, mode of administration, etc) (WHO CTR item 13, more details there.)	Select one per intervention - Drug (including placebo) - Device (including sham) - Biological/Vaccine - Procedure/Surgery - Radiation - Behavioral (e.g., Psychotherapy, Lifestyle Counseling) - Genetic (including gene transfer, stem cell and recombinant DNA) - Dietary Supplement (e.g., vitamins, minerals) - Other	Study	primaryPurposeCode	

ID	WHO.CTR Data Requirements		BRIDG Model Element		
	Data Item	Comment	Class	Attribute	Comment
18	Masking	Knowledge of intervention assignments (at least one of the following required: Intervention Model, Masking, Allocation. All may be required as part of Study Design under PL 110-85, Section 801) - Open: no masking is used. All involved know the identity of the intervention assignment. - Single Blind: one party, either the investigator or participant, is unaware of the intervention assignment; also called single-masked study. - Double Blind: two or more parties are unaware of the intervention assignment If Single Blind or Double Blind is selected, check the role(s) that are to be masked: Subject, Caregiver, Investigator or Outcomes Assessor.	InterventionalStudy	blindingSchemaCode	
19	Primary Outcome(s), Key Secondary Outcomes Outcomes include • Outcome name • Timepoints • Measure	Measure	StudyOutcomeMeasure	name	
20	Primary Outcome(s), Key Secondary Outcomes Outcomes include • Outcome name • Timepoints • Measure	Primary or Secondary?	StudyOutcomeMeasure	name	
21	Primary Outcome(s), Key Secondary Outcomes Outcomes include • Outcome name • Timepoints • Measure	Time Frame	StudyOutcomeMeasure	name	

ID	WHO.CTR Data Requirements		BRIDG Model Element		
	Data Item	Comment	Class	Attribute	Comment
22	Primary Outcome(s), Key Secondary Outcomes Outcomes include • Outcome name • Timepoints • Measure	Type of primary outcome or endpoint that the protocol is designed to evaluate. Select one. - N/A: not applicable - Safety: show if the drug is safe under conditions of proposed use - Efficacy: measure of an intervention's influence on a disease or health condition - Safety/Efficacy - Bio-equivalence: scientific basis for comparing generic and brand name drugs - Bio-availability: rate and extent to which a drug is absorbed or otherwise available to the treatment site in the body - Pharmacokinetics: the action of a drug in the body over a period of time including the process of absorption, distribution and localization in tissue, biotransformation, and excretion of the compound - Pharmacodynamics: action of drugs in living systems - Pharmacokinetics/dynamics	StudyOutcomeMeasure	typeCode	
23	Primary register (ASSIGNED ID NUMBER by the Registry) and Registry ID number (WHO CTR Item 1)	A unique identification given to a protocol by a registry.	DocumentIdentifier	identifier	
24	Primary register (ASSIGNED ID NUMBER by the Registry) and Registry ID number (WHO CTR Item 1)	A unique identification given to a protocol by a registry.	StudyRegistry	acronym	
25	Primary Sponsor (WHO CTR item 5)	Name of primary organization that oversees implementation of study and is responsible for data analysis. For applicable clinical trials, sponsor is defined in 21 CFR 50.3. Examples: National Institute of Allergy and Infectious Diseases, Bristol-Myers Squibb	Organization	name	
26	Primary Sponsor (WHO CTR item 5)	The individual, organization, group or other legal entity which takes responsibility for initiating, managing and/or financing a study. The Primary Sponsor is responsible for ensuring that the ensuring that the trial is properly registered. The Primary Sponsor may or may not be the main funder.	Organization	name	

ID	WHO.CTR Data Requirements		BRIDG Model Element		
	Data Item	Comment	Class	Attribute	Comment
27	Public Title - Title intended for the lay public in easily understood language. (WHO CTR item 9)	Definition: Protocol title intended for the lay public. Example: Safety Study of Recombinant Vaccinia Virus Vaccine to Treat Prostate Cancer	StudyProtocolDocument	publicTitle	
28	Recruitment Status (WHO CTR item 18)	StudyRecruitmentStatus: Status of finding and enrolling appropriate subjects (those selected on the basis of the protocol's inclusion and exclusion criteria) into a clinical study. StudyOverallStatus: Describes the comprehensive state of the study.	StudyRecruitmentStatus	statusCode	
29	Recruitment Status (WHO CTR item 18)	Overall accrual activity for the protocol. Select one. Not yet recruiting: participants are not yet being recruited Recruiting: participants are currently being recruited Enrolling by invitation: participants are being (or will be) selected from a predetermined population Active, not recruiting: study is ongoing (i.e., patients are being treated or examined), but participants are not currently being recruited or enrolled Completed: the study has concluded normally; participants are no longer being examined or treated (i.e., last patient's last visit has occurred) Suspended: recruiting or enrolling participants has halted prematurely but potentially will resume Terminated: recruiting or enrolling participants has halted prematurely and will not resume; participants are no longer being examined or treated Withdrawn: study halted prematurely, prior to enrollment of first participant	StudyOverallStatus	statusCode	
30	Scientific Title - Scientific title of the study as it appears in the protocol submitted for funding and ethical review. Include trial acronym if available. (WHO CTR Item 10)	Definition: Official name of the protocol provided by the study principal investigator or sponsor. Example: Phase 1 Study of Recombinant Vaccinia Virus That Expresses Prostate Specific Antigen in Metastatic Adenocarcinoma of the Prostate	Document	officialTitle	

ID	WHO.CTR Data Requirements		BRIDG Model Element		
	Data Item	Comment	Class	Attribute	Comment
31	Secondary Identifying Numbers (WHO CTR Item 3)	Protocol Identifying Number: Any of one or more unique codes that refers to a specific protocol. NOTE: There may be multiple numbers (Nat'l number, coop group number). [PRG; eudraCT] Other identifying numbers and issuing authorities besides the Primary Registry, if any. Include the sponsor name and sponsor-issued trial number (e.g., protocol number) if available. Also include other trial registries that have issued an identifying number to this trial. There is no limit on the number of Secondary identifying numbers that can be provided. (WHO)	DocumentIdentifier	identifier	
32	Secondary Sponsor(s) (WHO CTR item 6)	Other organizations (if any) providing support, including funding, design, implementation, data analysis and reporting. The data provider is responsible for confirming all collaborators before listing them. Provide up to 10 full names of collaborating organizations.	Organization	name	
33	Secondary Sponsor(s) (WHO CTR item 6)	Person is not defined in CT.gov	Organization	name	
34	Source(s) of Monetary or Material Support (WHO CTR item 4)	Funding Organization	Organization	name	
35	Source(s) of Monetary or Material Support (WHO CTR item 4)	Funding Person	Organization	name	
36	Study Type	Clinical trial design developed to compare treatment groups in a clinical trial. NOTE: The configuration usually requires randomization to one or more treatment arms, each arm being allocated a different (or no) treatment. Examples include: Parallel Group Design, Crossover Design, Factorial Designs. [from ICH E9]	Study	designConfigurationCode	
37	Study Type	A well-controlled study permits a comparison of subjects treated with the investigational drug with a suitable control population, so that the effect of the investigational drug can be determined and distinguished from other influences, such as spontaneous change, placebo effects, concomitant therapy, or observer expectations. [21 CFR 312.126]	InterventionalStudy	controlTypeCode	

ID	WHO.CTR Data Requirements		BRIDG Model Element		
	Data Item	Comment	Class	Attribute	Comment
38	Study Type	Definition: Nature of the investigation. Select one. Interventional: studies in human beings in which individuals are assigned by an investigator based on a protocol to receive specific interventions. Subjects may receive diagnostic, therapeutic or other types of interventions. The assignment of the intervention may or may not be random. The individuals are then followed and biomedical and/or health outcomes are assessed. Observational: studies in human beings in which biomedical and/or health outcomes are assessed in pre-defined groups of individuals. Subjects in the study may receive diagnostic, therapeutic, or other interventions, but the investigator does not assign specific interventions to the subjects of the study. Expanded Access: records describing the procedure for obtaining an experimental drug or device for patients who are not adequately treated by existing therapy, who do not meet the eligibility criteria for enrollment, or who are otherwise unable to participate in a controlled clinical study. Expanded Access records are	Study	~ derived based on specialization type	

ID	WHO.CTR Data Requirements		BRIDG Model Element		
	Data Item	Comment	Class	Attribute	Comment
39	Study Type - Purpose	Reason for the protocol - Treatment: protocol designed to evaluate one or more interventions for treating a disease, syndrome or condition - Prevention: protocol designed to assess one or more interventions aimed at preventing the development of a specific disease or health condition - Diagnostic: protocol designed to evaluate one or more interventions aimed at identifying a disease or health condition - Supportive Care: protocol designed to evaluate one or more interventions where the primary intent is to maximize comfort, minimize side effects or mitigate against a decline in the subject's health or function. In general, supportive care interventions are not intended to cure a disease. - Screening: protocol designed to assess or examine methods of identifying a condition (or risk factors for a condition) in people who are not yet known to have the condition (or risk factor). - Health Services Research: protocol designed to evaluate the delivery, processes, management, organization or financing of health	Study	primaryPurposeCode	
40	Study Type - Who is blinded	Registries may collect data on who is masked (the subjects, therapist or clinician, assessor or data analyst) If Single Blind or Double Blind is selected, check the role(s) that are to be masked: Subject, Caregiver, Investigator or Outcomes Assessor.	InterventionalStudy	blindedRoleCode	
41	Study Type.Phase (WHO CTR item 15)	Phase of investigation, as defined by the US FDA for trials involving investigational new drugs. (N/A, Phase 0, Phase 1, Phase 1/Phase2, Phase 2, Phase 2/Phase 3, Phase 3, Phase 4)	Study	phaseCode	

ID	WHO.CTR Data Requirements		BRIDG Model Element		
	Data Item	Comment	Class	Attribute	Comment
42	Study Type-Assignment	Plan for the precise procedure to be followed in a clinical trial, including planned and actual timing of events, choice of control group, method of allocating treatments, blinding methods; assigns a subject to pass through one or more epochs in the course of a trial. Specific design elements, e.g., crossover, parallel; dose-escalation [Modified from Pocock, Clinical Trials: A Practical Approach] See Trial Design Model. See also, arm, epoch, and visit.	Study	designConfigurationCode	
43	Target Sample Size	Number of subjects in the trial. A "Type" menu is also included, with options Anticipated and Actual. For active studies, set Type to Anticipated and specify the expected enrollment, updating the number as needed over the course of the study. Upon study completion, change Type to Actual and update the enrollment if necessary.	Study	targetAccuralNumberRange	

ID	EMEA Data Requirement			BRIDG Model Element		
	Form Ref	Field Name	Comments	Class	Attribute	Comment
1	A.1	Application MS (member state)	Calculated fields derived from Application NCA country. Not stored in the database.	Organization	postalAddress	
2	A.1	Application NCA (National Competent Authority)	The NCA organisation that will be responsible for entering the data to the EudraCT database. This information will be used by the user access security system to ensure that NCAs can only enter and edit Applications for which they have responsibility.	Organization	name	
3	A.2	EudraCT number	yyyy-nnnnnn-cc. yyyy = year. nnnnnn is sequential within year. cc are check digits. [AA and A1 are the concatenated table key]	DocumentIdentifier	identifier	
4	A.3	Full title of the trial	Free text. Field size changed from 500 to 2000 at 3.0.1	Document	officialTitle	
5	**A.3.1**	Title of the trial for lay people		StudyProtocolDocument	publicTitle	
6	**A.3.2**	Abbreviated title of trial	As ICH A.2.3.1 Study Name.	Study	acronym	
7	A.4.1	Sponsor protocol number	As ICH A.2.3.2 Sponsor Study Number.	DocumentIdentifier	identifier	
8	A.4.2	Sponsor protocol version	The sponsors version number for this protocol	Document	revisionNumberText	
9	A.4.3	Sponsor protocol version date	YYYYMMDD. The date of the this version of the sponsor's protocol	Document	versionDate	Proposed addition to BRIDG
10	A.5.1	ISRCTN number	Format ISRCTN99999999	DocumentIdentifier	identifier	
11	**A.5.2**	US NCT number	Roughly, NCT numbers are 8 digits, ascending and correlated with registration date. More specifically, NCT00000100 - NCT00006520 are sequential with occasional random gaps (caused by deletions, errors, etc...) then we got a little smarter and started	DocumentIdentifier	identifier	
12	**A.5.3**	WHO UTRN		DocumentIdentifier	identifier	
13	**A.5.4**	Other Identifier Name	Repeating as a pair with identifier	DocumentIdentifier	identifier	
14	**A.5.4**	Other Identifier	Repeating as a pair with name	DocumentIdentifier	identifier	
15	A.6	Is resubmission	Resubmission question	Submission	typeCode	
16	**A.8**	PIP Decision number	Format: P/xx/yyyy, where xx is a sequential number that may extend to 3 digits and yyyy is the year.	RegulatoryApplication	identifier	

ID	EMEA Data Requirement			BRIDG Model Element		
	Form Ref	Field Name	Comments	Class	Attribute	Comment
17	B.1.1	Sponsor Organisation	Name of organisation managing this trial. EV Simple DB mahname has 100 – use the same as EV. See row 10dd	Organization	name	
18	B.1.2.1	Sponsor Contact Given name	Field lengths are as per ICH A.3.1.3c, A.3.1.3d and A.3.1.3e Sender Identifier	Person	name	
19	B.1.2.2	Sponsor Contact Middle name	Field lengths are as per ICH A.3.1.3c, A.3.1.3d and A.3.1.3e Sender Identifier	Person	name	
20	B.1.2.3	Sponsor Contact Family Name	Field lengths are as per ICH A.3.1.3c, A.3.1.3d and A.3.1.3e Sender Identifier	Person	name	
21	B.1.3.1	Sponsor Street Address	ICH A.3.1.4a (Sender Address)	OrganizationalContact	postalAddress	
22	B.1.3.2	Sponsor Town/City	Town/city only in database. As EV city field in DD_MAH.	OrganizationalContact	postalAddress	
23	B.1.3.3	Sponsor Post Code	ICH A.3.1.4d (Sender Address)	OrganizationalContact	postalAddress	
24	B.1.3.4	Sponsor Country	EUTCT ID of the country May be from any country in the world.	OrganizationalContact	postalAddress	
25	B.1.4	Sponsor Telephone	ICH ICSR DTD Version 2.1 separates Tel No. (10AN), extension (5AN) Telephone country code (3AN)(ICH A.3.1.4f,g,h respectively)	OrganizationalContact	telecomAddress	
26	B.1.5	Sponsor Fax	ICH ICSR DTD Version 2.1 separates Fax No. (10AN), extension (5AN) and Fax country code (3AN).(ICH A.3.1.4i,j,k respectively).	OrganizationalContact	telecomAddress	
27	B.1.6	Sponsor Email	ICH A.3.1.4l	OrganizationalContact	telecomAddress	
28	B.3.1 and B.3.2	Sponsor Status	Reference table. Commercial or Non-commercial	Organization	typeCode	
29	B.2.1	Legal Rep Organisation	There can be one and only one legal representative for a sponsor.	Organization	name	
30	B.2.2.1	Legal Rep Given Name	Field lengths are as per ICH A.3.1.3c, A.3.1.3d and A.3.1.3e Sender Identifier.	Person	name	
31	B.2.2.2	Legal Rep Middle name	Field lengths are as per ICH A.3.1.3c, A.3.1.3d and A.3.1.3e Sender Identifier.	Person	name	
32	B.2.2.3	Legal Rep Family Name	Field lengths are as per ICH A.3.1.3c, A.3.1.3d and A.3.1.3e Sender Identifier.	Person	name	
33	B.2.3.1	Legal Rep Street Address	ICH A.3.1.4a (Sender Address)	OrganizationalContact	postalAddress	
34	B.2.3.2	Legal Rep Town/City	Town/city only. No detailed address held in the database. As EV city field in DD_MAH.	OrganizationalContact	postalAddress	
35	B.2.3.3	Legal Rep Post Code	ICH A.3.1.4d (Sender Address)	OrganizationalContact	postalAddress	

ID	EMEA Data Requirement			BRIDG Model Element		
	Form Ref	Field Name	Comments	Class	Attribute	Comment
36	B.2.3.4	Legal Rep Country	EUTCT ID of the country. Must be from the EEA list only	OrganizationalContact	postalAddress	
37	B.2.4	Legal Rep Telephone	ICH ICSR DTD Version 2.1 separates Tel No. (10AN), extension (5AN) Telephone country code (3AN)(ICH A.3.1.4f,g,h respectively)	OrganizationalContact	telecomAddress	
38	B.2.5	Legal Rep Fax	ICH ICSR DTD Version 2.1 separates Fax No. (10AN), extension (5AN) and Fax country code (3AN).(ICH A.3.1.4i,j,k respectively).	OrganizationalContact	telecomAddress	
39	B.2.5	Legal Rep Email	ICH A.3.1.4l	OrganizationalContact	telecomAddress	
40	**B.4.1**	Source of Monetary or Material Support organisation name	Repeating with B.4.2	Organization	name	
41	**B.4.2**	Source of Monetary or Material Support country	EUTCT ID of the country. May be from any country in the world.	Organization	postalAddress	
42	**B.5.1**	Further information contact Organisation		Organization	name	
43	**B.5.2**	Further information contact name	Field lengths are as per ICH A.3.1.3c, A.3.1.3d and A.3.1.3e Sender Identifier.	StudyColleague	roleCode	
44	**B.5.3.1**	Contact point for further information on the trial Street Address	ICH A.3.1.4a (Sender Address)	StudyColleague	postalAddress	
45	**B.5.3.2**	Further information contact Town/City	Town/city only. No detailed address held in the database. As EV city field in DD_MAH.	StudyColleague	postalAddress	
46	**B.5.3.3**	Further information contact Post Code	ICH A.3.1.4d (Sender Address)	StudyColleague	postalAddress	
47	**B.5.3.4**	Further information contact Country	EUTCT ID of the country. Must be from the EEA list only	StudyColleague	postalAddress	
48	**B.5.4**	Further information contact Telephone	ICH ICSR DTD Version 2.1 separates Tel No. (10AN), extension (5AN) Telephone country code (3AN)(ICH A.3.1.4f,g,h respectively)	StudyColleague	telecomAddress	
49	**B.5.5**	Further information contact Fax	ICH ICSR DTD Version 2.1 separates Fax No. (10AN), extension (5AN) and Fax country code (3AN).(ICH A.3.1.4i,j,k respectively).	StudyColleague	telecomAddress	
50	**B.5.6**	Further information contact E-mail	ICH A.3.1.4l	StudyColleague	telecomAddress	
51	**B.5.7.1**	SUSAR Reporting to NCAs		RegulatoryAuthority	juridictionCode	
52	**B.5.7.2**	SUSAR Reporting to EVCTM		RegulatoryAuthority	juridictionCode	
53	**B.5.8.1**	EV Sender ID organisation		Organization	name	
54	**B.5.8.2**	EV Sender ID		Organization	identifier	

ID	EMEA Data Requirement			BRIDG Model Element		
	Form Ref	Field Name	Comments	Class	Attribute	Comment
55	C.1.1, C.1.2 and C.1.3	CA (Competent Authority) Applicant Type	Identification of the CA applicant for this CT in this MS. Selection by drop down list : Sponsor or Legal representative of the Sponsor or Person or organisation authorised by the Sponsor	OrganizationRelationship	typeCode	
56	C.1.4.1	CA Applicant Organisation		Organization	name	
57	C.1.4.2.1	CA Applicant Given Name		Person	name	
58	C.1.4.2.2	CA Applicant Middle name		Person	name	
59	C.1.4.2.3	CA Applicant Family Name		Person	name	
60	C.1.4.3.1	CA Applicant Street Address	ICH A.3.1.4a (Sender Address)	OrganizationalContact	postalAddress	
61	C.1.4.3.2	CA Applicant Town/City	Town/city only. No detailed address. As EV city field in DD_MAH.	OrganizationalContact	postalAddress	
62	C.1.4.3.3	CA Applicant Post Code	ICH A.3.1.4d (Sender Address)	OrganizationalContact	postalAddress	
63	C.1.4.3.4	CA Applicant Country	EUTCT ID of the country. Full worldwide list from Version 4.0.0	OrganizationalContact	postalAddress	
64	C.1.4.4	CA Applicant Telephone	ICH ICSR DTD Version 2.1 separates Tel No. (10AN), extension (5AN) Telephone country code (3AN)(ICH A.3.1.4f,g,h respectively)	OrganizationalContact	telecomAddress	
65	C.1.4.5	CA Applicant Fax	ICH ICSR DTD Version 2.1 separates Fax No. (10AN), extension (5AN) and Fax country code (3AN).(ICH A.3.1.4i,j,k respectively).	OrganizationalContact	telecomAddress	
66	C.1.4.6	CA Applicant Email	ICH A.3.1.4l	OrganizationalContact	telecomAddress	
67	C.2.1, C.2.2, C.2.3 and C.2.4	IEC (Independent Ethics Committee) Applicant Type	Identification of the IEC applicant for this CT in this MS. Selection by radio button or drop-down list.	OrganizationRelationship	typeCode	
68	C.2.5.1	IEC Applicant Organisation		Organization	name	
69	C.2.5.2.1	IEC Applicant Given Name		Person	name	
70	C.2.5.2.2	IEC Applicant Middle name		Person	name	
71	C.2.5.2.3	IEC Applicant Family Name		Person	name	
72	C.2.5.3.1	IEC Applicant Street Address	ICH A.3.1.4a (Sender Address)	OrganizationalContact	postalAddress	
73	C.2.5.3.2	IEC Applicant Town/City	Town/city only. No detailed address. As EV city field in DD_MAH.	OrganizationalContact	postalAddress	
74	C.2.5.3.3	IEC Applicant Post Code	ICH A.3.1.4d (Sender Address)	OrganizationalContact	postalAddress	
75	C.2.5.3.4	IEC Applicant Country	EUTCT ID of the country. Must be from the EEA list only	OrganizationalContact	postalAddress	

ID	EMEA Data Requirement			BRIDG Model Element		
	Form Ref	Field Name	Comments	Class	Attribute	Comment
76	C.2.5.4	IEC Applicant Telephone	ICH ICSR DTD Version 2.1 separates Tel No. (10AN), extension (5AN) Telephone country code (3AN)(ICH A.3.1.4f,g,h respectively)	OrganizationalContact	telecomAddress	
77	C.2.5.5	IEC Applicant Fax	ICH ICSR DTD Version 2.1 separates Fax No. (10AN), extension (5AN) and Fax country code (3AN).(ICH A.3.1.4i,j,k respectively).	OrganizationalContact	telecomAddress	
78	C.2.5.6	IEC Applicant Email	ICH A.3.1.4l	OrganizationalContact	telecomAddress	
79	D.1.1	IMP sequence number	Unique sequence number for the repeating products. Format: PRnn	Material	identifier	
80	D.1.2 and D.1.3	IMP Category	Field to describe the role of the product in the trial.	StudyAgent	functionCode	
81	D.2.1.1.1	IMP Trade name	Product Tradename	Material	name	
82	D.2.1.1.1.1	EV Identifiable Product Code		Product	nameCode	
83	D.2.1.1.2	MA Holder	MA holder	Organization	name	
84	D.2.1.1.3	MA number	MA number - equivalent to an NDA (new drug application).	RegulatoryAssessment	identifier	
85	D.2.1.1.4.1	IMP modified specification	If Y to D.2.1.1.4 this is the text describing the modification	Document	text	
86	D.2.1.2	Country granting MA	EUTCT ID of the country that granted the MA. May be from any country in the world.	RegulatoryAuthority	juridictionCode	
87	D.2.2.4.1	IMP identification other specification	To be completed only if the question above (D.2.2.4) is set to 'Y'	RegulatoryAssessment	identifier	
88	D.2.3.1	Full IMPD submitted		Document	typeCode	
89	D.2.3.2	Simplified IMPD submitted		Document	typeCode	
90	D.2.3.3	Only SmPC (Summary of Product Characteristics) submitted		Document	typeCode	
91	D.2.5.1	Orphan drug number	If row 48 = Y then this is the orphan product designation number for this product and indication. Community register on orphan medicinal products format EU/n/nn/nnn. *NOTE: # is assigned by EMA*	RegulatoryAssessment	identifier	
92	D.2.6.1.1	SA (Scientific Advice) from CHMP		RegulatoryAuthority	juridictionCode	
93	D.2.6.1.2	SA from NCA		RegulatoryAuthority	juridictionCode	
94	D.3.1	IMP Name	In the absence of a Tradename this is the name routinely used by the sponsor in the clinical trial documentation e.g. patient information leaflet, protocol, IB. If the sponsor does not have a specific product name, and only the active substance name or c	Material	name	

ID	EMEA Data Requirement			BRIDG Model Element		
	Form Ref	Field Name	Comments	Class	Attribute	Comment
95	D.3.2	IMP Code	Code defined by the sponsor, potentially used in case of combination of drugs and devices but not routinely anticipated. This field is not required if the Tradename of an authorised product (in the EEA) has been provided. This field may be blank if no pr	Material	name	
96	D.3.3	IMP ATC Code	7-character alphanumeric at level 4. this should only be entered when the product is used in the clinical trial within the terms of the marketing authorisation.	Product	classCode	
97	D.3.4	IMP Pharmaceutical Form		Material	formCode	
98	**D.3.4.1**	Specific paediatric formulation		DefinedActivity	subcategoryCode	
99	D.3.5	Maximum duration of treatment	Pre-3.0.1 max duration and dose was in Section G and general to the whole trial. From 3.0.1 these fields are for each specific IMP	PlannedActivity	plannedDuration	
100	D.3.6.1	First dose in FIH (First In Human) dose allowed		DefinedSupstanceAdministration	dose	
101	D.3.6.1	First dose in FIH Dose per Day or Total		DefinedSupstanceAdministration	dailyDoseTotal	
102	D.3.6.1	First dose in FIH Total Dose Number		DefinedSupstanceAdministration	repeatQuantity	
103	D.3.6.1	First dose in FIH Total Dose Unit	Use EV LK_CONCENTRATIONUNIT lookup table– drop down list (ICH “measureunit” + additional values). Longest unit name is 38 chrs: IU/mg international unit(s)/milligram	DefinedSupstanceAdministration	dailyDoseTotal	
104	D.3.6.1	First dose in FIH RoA		DefinedSupstanceAdministration	routOfAdministrationCode	
105	D.3.6.2	Maximum dose per Day or Total		DefinedSupstanceAdministration	dailyDoseTotal	
106	D.3.6.2	Maximum dose Total Dose Number		DefinedSupstanceAdministration	repeatQuantity	
107	D.3.6.2	Maximum dose Total Dose Unit	Use EV LK_CONCENTRATIONUNIT lookup table– drop down list (ICH “measureunit” + additional values). Longest unit name is 38 chrs: IU/mg international unit(s)/milligram	DefinedSupstanceAdministration	dose	
108	D.3.6.2	Maximum dose RoA		DefinedSupstanceAdministration	routOfAdministrationCode	
109	D.3.7	IMP Routes of Administration	Multi select	DefinedSupstanceAdministration	routOfAdministrationCode	

ID	EMEA Data Requirement			BRIDG Model Element		
	Form Ref	Field Name	Comments	Class	Attribute	Comment
110	D.3.8	AS INN	The International Non-proprietary name for this active substance. ICH B.4.k.2.2 activesubstancename is 100AN. Pre 3.0.1 there were two fields for an INN and a Proposed INN. These two fields were combined into one at 3.0.1	Material	name	
111	D.3.9.1	AS CAS (Chemical Abstract Service) number		Product	classCode	
112	D.3.9.2	AS current sponsor code	The current code in use by the sponsor for this active substance.	Product	nameCode	
113	D.3.9.3	AS other descriptive name	Any other descriptive name for this active substance. Size increased to 500 chars in V8	Material	name	
114	**D3.9.4**	EV (EudraVigilance) Substance Code	EV code of substance - field in use from 3.0.1	Material	name	
115	**D.3.9.5**	AS molecular formula		Material	description	
116	**D.3.9.6**	AS description		Material	description	
117	D.3.11.1	Chemical origin AS	Does the product contain an active substance of chemical origin ?	ProductPart	activeIngredientIndicator	
118	D.3.11.2	Biological origin AS	Does the product contain an active substance of biological or biotechnological origin ?	ProductPart	activeIngredientIndicator	
119	**D.3.11.3**	Advanced Therapy MP		Product	classCode	
120	D.3.11.3.1	Somatic cell therapy MP	Does the proposed clinical trial entail a somatic cell therapy medicinal product ?	Product	classCode	
121	D.3.11.3.2	Gene therapy MP	Does the proposed clinical trial entail a gene therapy medicinal product ?	Product	classCode	
122	**D.3.11.3.3**	Tissue Engineered MP		Product	classCode	
123	**D.3.11.3.4**	Combination ATIMP		Product	classCode	
124	**D.3.11.3.5**	CAT (committee for Advanced therapies) Classification issued		Product	classCode	
125	**D.3.11.3.5.1**	CAT Classification		Product	classCode	
126	**D.3.11.4**	Combination product including device		Product	typeCode	
127	D.3.11.5	Radiopharmaceutical MP	Does the proposed clinical trial entail a radiopharmaceutical medicinal product ?	Product	classCode	
128	D.3.11.6	Immunological MP	Does the proposed clinical trial entail an immunological medicinal product (such as a vaccine, allergen, immune serum, etc) ?	Product	classCode	
129	D.3.11.7	Plasma derived MP	Plasma derived medicinal product	Product	classCode	
130	D.3.11.8	Extractive MP	Other extractive medicinal product	Product	classCode	
131	**D.3.11.9**	Recombinant MP		Product	classCode	

ID	EMEA Data Requirement			BRIDG Model Element		
	Form Ref	Field Name	Comments	Class	Attribute	Comment
132	D.3.11.10	GMO (Genetically Modified Organism) MP	Does the proposed clinical trial entail a medicinal product containing GMOs?	Product	classCode	
133	D.3.11.10.1	GMP MP Auth granted	If row 78 = Y is this authorised for contained use ?	RegulatoryAssessment	statusCode	Proposed addition to BRIDG
134	D.3.11.10.2	GMP MP Auth pending	If row 78 = Y is authorisation pending ?	RegulatoryAssessment	statusCode	Proposed addition to BRIDG
135	D.3.11.11	Herbal MP	Does the proposed clinical trial entail a herbal medicinal product?	Product	typeCode	
136	D.3.11.12	Homeopathic MP	Does the proposed clinical trial entail a homeopathic medicinal product?	Product	typeCode	
137	D.3.11.13	Other MP		Product	typeCode	
138	D.3.11.13.1	Other MP Specification		Product	typeCode	
139	**D.3.12**	Mode of action	How the active substance works Free text (To respond to HMA's requests)	ProductPart	actionMode	Proposed addition to BRIDG
140	**D.3.13**	First in Human	(To respond to HMA's requests)	StudyAgent	firstInHumanIndicator	Proposed addition to BRIDG
141	**D.3.13.1**	First in Human Risk Factors	(To respond to HMA's requests)	StudyAgent	firstInHumanRiskFactor	Proposed addition to BRIDG
142	D.4.1.1	Somatic Cell Therapy origin autologous	If D.3.11.3 = Y is the origin of the cells autologous ?	DefinedActivity	nameCode	
143	D.4.1.2	Somatic Cell Therapy origin allogeneic	If D.3.11.3 = Y is the origin of the cells allogeneic ?	DefinedActivity	nameCode	
144	D.4.1.3	Somatic Cell Therapy origin xenogeneic	If D.3.11.3 = Y is the origin of the cells xenogeneic ?	DefinedActivity	nameCode	
145	D.4.1.3.1	Somatic Cell Therapy xenogeneic species	If D.5.1.3 = Y then enter here the species of origin of xenogeneic cells	DefinedActivity	nameCode	
146	D.4.2.1	Somatic Cell Therapy type stem	If D.3.11.3 = Y then is the type of cells stem ?	DefinedActivity	nameCode	
147	D.4.2.2	Somatic Cell Therapy type differentiated	If D.3.11.3 = Y then is the type of cells differentiated ?	DefinedActivity	nameCode	
148	D.4.2.2.1	Type of differentiated cells	If D.5.2.2 = Y then this holds the description of the differentiated cell type (eg keratinocytes, fibroblasts, chondrocytes, etc).	DefinedActivity	description	
149	D.4.2.3	Somatic Cell Therapy type other	A cell therapy type not identified in D.5.1.1 to D.5.2.2.1	DefinedActivity	nameCode	
150	D.4.2.3.1	Somatic Cell Therapy type other specification	If D.5.2.3 = Y then this holds a description for cell types other than stem and differentiated..	DefinedActivity	description	
151	D.5.1	Gene therapy gene(s) of interest	Free text list of the genes of interest	DefinedActivity	description	
152	D.5.2	Gene therapy in-vivo		DefinedActivity	nameCode	
153	D.5.3	Gene therapy ex-vivo		DefinedActivity	nameCode	
154	D.5.4.1	Gene therapy nucleic acid		DefinedActivity	nameCode	
155	D.5.4.1.1	Gene therapy naked		DefinedActivity	nameCode	

ID	EMEA Data Requirement			BRIDG Model Element		
	Form Ref	Field Name	Comments	Class	Attribute	Comment
156	D.5.4.1.2	Gene therapy complexed		DefinedActivity	nameCode	
157	D.5.4.2	Gene therapy viral vector		DefinedActivity	nameCode	
158	D.5.4.2.1	Gene therapy viral vector type		DefinedActivity	nameCode	
159	D.5.4.3	Gene Therapy other	Gene therapy other than Nucleic (Line 91=N)) or Viral (Line 94=N)	DefinedActivity	nameCode	
160	D.5.4.3.1	Gene therapy other specification	If D.6.4.3 = Y then enter here free text for any other gene transfer product.	DefinedActivity	nameCode	
161	D.5.5	GM cells	If D.3.11.4 = Y does this gene therapy involve genetically modified cells ?	Product	nameCode	
162	D.5.5.1	GM cells origin autologous	If D.6.5 =Y is the origin of the genetically modified cells autologous ?	DefinedActivity	nameCode	
163	D.5.5.2	GM cells origin allogeneic	If D.6.5 =Y is the origin of the genetically modified cells allogeneic ?	DefinedActivity	nameCode	
164	D.5.5.3	GM cells origin xenogeneic	If D.6.5 =Y is the origin of the genetically modified cells xenogeneic ?	DefinedActivity	nameCode	
165	D.5.5.3.1	GM cells xenogeneic species	If D.6.5.3 = Y then enter here the species of origin of xenogeneic cells	DefinedActivity	nameCode	
166	D.5.5.4	GM cells Other specification	Enter here free text for the type of genetically modified cells (eg haematopoietic stem cells, etc)	DefinedActivity	description	
167	**D.6.1.1**	Tissue Engineered origin autologous		DefinedActivity	nameCode	
168	**D.6.1.2**	Tissue Engineered origin allogeneic		DefinedActivity	nameCode	
169	**D.6.1.3**	Tissue Engineered origin xenogeneic		DefinedActivity	nameCode	
170	**D.6.1.3.1**	Tissue Engineered xenogeneic species		DefinedActivity	nameCode	
171	**D.6.2.1**	Tissue Engineered type stem		Product	nameCode	
172	**D.6.2.2**	Tissue Engineered type differentiated		Product	nameCode	
173	**D.6.2.2.1**	Tissue Engineered differentiated specification		Product	description	inherited from Material
174	**D.6.2.3**	Tissue Engineered Other		Product	nameCode	
175	**D.6.2.3.1**	Tissue Engineered Other specification		Product	description	inherited from Material
176	**D.7.1**	Device description		material	material.description	
177	**D.7.2**	Device name		material	material.name	
178	**D.7.3**	Device implantable		Product	typeCode	
179	**D.7.4.1**	Contains medical device		Product	typeCode	
180	**D.7.4.2**	Contains Bio-materials		Product	typeCode	
181	**D.7.4.3**	Contains Scaffolds		Product	typeCode	
182	**D.7.4.4**	Contains Matrices		Product	typeCode	
183	**D.7.4.5**	Device Other		Product	typeCode	
184	**D.7.4.5.1**	Device Other specification		Product	description	inherited from Material
185	D.8.2	Placebo sequence number	Format: PLnn	Product	identifier	inherited from Material
186	D.8.3	Placebo Pharmaceutical form		material	formCode	inherited from Material
187	D.8.4	Placebo Route of administration	NOTE: This field repeats. There may be more than one Route of Administration for one placebo	DefinedSupstanceAdministration	routOfAdministrationCode	inherited from Material

ID	EMEA Data Requirement			BRIDG Model Element		
	Form Ref	Field Name	Comments	Class	Attribute	Comment
188	D.8.5	Related IMP sequence number	Product sequence number (row 31) for the products (IMPs) for which this is a placebo.	Product	identifier	inherited from Material
189	D.8.5.2	Placebo identical to IMP		Product	nameCode	
190	D.8.5.2.1	Placebo major ingredients		Product	nameCode	
191	**D.9.3**	IMP sequence number	Product sequence number for the products (IMPs) for which no responsible site is required	Product	identifer	inherited from Material
192	**D.9.4**	Placebo sequence number	Product sequence number for the products (IMPs) for which no responsible site is required	Product	identifer	inherited from Material
193	D.9.2.1 and D.9.2.2	Responsible Site Role	Who is authorizing the release of the Final packaged & labeled product?	Performer	typeCode	inherited from Material
194	D.9.2.2	Responsible Site Organisation	Name of the organisation within the Community responsible for the release of the IMP. Each IMP in turn needs to be referred to and identified for ID F.1.3 ICH A.3.1.2 Sender Identifier has 60 and EV Simple DB mahname has 100 – use the same as EV.	Organization	name	inherited from Material
195	D.9.2.4.1	Responsible Site Street Address	ICH A.3.1.4a (Sender Address)	Organization	postalAddress	inherited from Material
196	D.9.2.4.2	Responsible Site Town/City	As EV city field in DD_MAH.	Organization	postalAddress	inherited from Material
197	D.9.2.4.3	Responsible Site Post Code	ICH A.3.1.4d (Sender Address)	Organization	postalAddress	inherited from Material
198	D.9.2.4.4	Responsible Site Country	EUTCT ID of the country. Must be from the EEA/MS list only	Organization	postalAddress	inherited from Material
199	D.9.2.5	Manufacturer authorisation number	Change of meaning of this field from 3.0.1	RegulatoryAssessment	identifier	
200	D.9.2.5.1	Reason for no authorisation		RegulatoryAssessment	assessmentReasonCode	Proposed addition to BRIDG
201	D.9.2	Product sequence number	Product sequence number (row 31) for the products (IMPs) for which this is the responsible site.	Product	identifer	inherited from Material
202	D.9.2	Placebo sequence number		Product	identifer	inherited from Material
203	E.1.1	Medical condition	Free text entry	Study	diseaseCode	
204	**E.1.1.1**	Medical condition in lay language		Study	diseaseCode	
205	E.1.2	MedDRA Version	MedDRA dictionary version.	Study	diseaseCode	
206	E.1.2	MedDRA Level	MedDRA level One of HLGT;HLT;LLT;PT;SOC	Study	diseaseCode	
207	E.1.2	MedDRA Code	MedDRA code	Study	diseaseCode	
208	E.1.2	MedDRA Term	MedDRA term	Study	diseaseCode	
209	E.1.2	MedDRA EUTCT ID		Study	diseaseCode	
210	E.2.1	Trial main objective		StudyObjective	description	

ID	EMEA Data Requirement			BRIDG Model Element		
	Form Ref	Field Name	Comments	Class	Attribute	Comment
211	E.2.2	Trial secondary objective	Included within a single text string (form guidance). (DB Guidance says “repeat as necessary”)	StudyObjective	description	
212	E.3	Principal inclusion criteria	Included within a single text string (form guidance). (DB Guidance says “repeat as necessary”)	DefinedInclusionCriteria	nameCode	inherited from Defined Activity
213	E.4	Principal exclusion criteria	Included within a single text string (form guidance). (DB Guidance says “repeat as necessary”)	DefinedExclusionCriteria	nameCode	inherited from Defined Activity
214	E.5.1	Primary end points	Included within a single text string (form guidance). Repeating	studyOutcomeMeasure	name	
215	**E.5.1.1**	Primary end point timepoint	Linked to each endpoint	studyOutcomeMeasure	timeFrameText	
216	**E.5.2**	Secondary end point	Included within a single text string (form guidance). Repeating	studyOutcomeMeasure	name	
217	**E.5.2.1**	Secondary end point timepoint	Linked to each endpoint	studyOutcomeMeasure	timeFrameText	
218	E.6	Trial scope		studyOutcomeMeasure	typeCode	
219	E.6.1	Trial scope Diagnosis		studyOutcomeMeasure	typeCode	
220	E.6.2	Trial scope Prophylaxis		studyOutcomeMeasure	typeCode	
221	E.6.3	Trial scope Therapy		studyOutcomeMeasure	typeCode	
222	E.6.4	Trial scope Safety		studyOutcomeMeasure	typeCode	
223	E.6.5	Trial scope Efficacy		studyOutcomeMeasure	typeCode	
224	E.6.6	Trial scope Pharmacokinetic		studyOutcomeMeasure	typeCode	
225	E.6.7	Trial scope Pharmacodynamic		studyOutcomeMeasure	typeCode	
226	E.6.8	Trial scope Bioequivalence		studyOutcomeMeasure	typeCode	
227	E.6.9	Trial scope Dose response		studyOutcomeMeasure	typeCode	
228	E.6.10	Trial scope Pharmacogenetic	New field at 3.0.1	studyOutcomeMeasure	typeCode	
229	E.6.11	Trial scope Pharmacogenomic		studyOutcomeMeasure	typeCode	
230	E.6.12	Trial scope Pharmacoeconomic		studyOutcomeMeasure	typeCode	
231	E.6.13	Trial scope Other		studyOutcomeMeasure	typeCode	
232	E.6.13.1	Trial scope Other specification	If line E.6.13 =”Y” then specify here.	studyOutcomeMeasure	typeCode	
233	E.7.1	Trial type Human pharmacology (Phase I)		Study	phaseCode	
234	E.7.1.1	Trial type First administration to humans		Study	typeCode	Proposed addition to BRIDG
235	E.7.1.2	Trial type Bioequivalence Study		Study	typeCode	Proposed addition to BRIDG
236	E.7.1.3	Trial type Other		Study	typeCode	Proposed addition to BRIDG
237	E.7.1.3.1	Trial type Other specification	If line E.7.1.3 = ‘Y’ then specify here	Study	typeCode	Proposed addition to BRIDG
238	E.7.2	Trial type Therapeutic Exploratory (Phase II)		Study	typeCode	Proposed addition to BRIDG
239	E.7.3	Trial type Therapeutic Confirmatory (Phase III)		Study	typeCode	Proposed addition to BRIDG
240	E.7.4	Trial type Therapeutic Use (Phase IV)		Study	typeCode	Proposed addition to BRIDG
241	E.8.1.3	Trial design Single blind		PlannedRandomizationBookAllocation	blindedDescription	Inherited from Planned Activity
242	E.8.1.4	Trial design Double blind		PlannedRandomizationBookAllocation	blindedDescription	Inherited from Planned Activity
243	E.8.1.5	Trial design Parallel group		StratumGroup	groupNumber	
244	E.8.2.1	Comparator another MP		Product	nameCode	
245	E.8.2.2	Comparator a placebo		Product	nameCode	
246	E.8.2.3	Other comparator		Product	nameCode	

ID	EMEA Data Requirement			BRIDG Model Element		
	Form Ref	Field Name	Comments	Class	Attribute	Comment
247	E.8.2.3.1	Other comparator specification	If line E.8.2.3 = 'Y' then specify here	Product	description	inherited from Material
248	**E.8.2.4**	Number Treatment Arms		Arm	typeCode	
249	E.8.7	Trial has data monitoring committee	New field in 3.0.1	Service	typeCode	
250	E.8.9.1	Estimated trial duration in MS years		Study	duration	Proposed addition to BRIDG
251	E.8.9.1	Estimated trial duration in MS months		Study	duration	Proposed addition to BRIDG
252	E.8.9.1	Estimated trial duration in MS days	New field at 3.0.1	Study	duration	Proposed addition to BRIDG
253	E.8.9.2	Estimated trial duration worldwide years		Study	duration	Proposed addition to BRIDG
254	E.8.9.2	Estimated trial duration worldwide months		Study	duration	Proposed addition to BRIDG
255	E.8.9.2	Estimated trial duration worldwide days	New field at 3.0.1	Study	duration	Proposed addition to BRIDG
256	F.1.1	Population under eighteen	If the trial population includes subjects < 18 years: A statement that this clinical trial carried out outside the EEA will be conducted in accordance with the ethical requirements of Directive 2001/20/EC and includes measures to minimise pain and distres	Study	populationDescription	
257	**New**	Population number under eighteen		Study	populationDescription	
258	F.1.1.1	Population in utero		Study	populationDescription	
259	**F.1.1.1.1**	Population number in utero		Study	populationDescription	
260	F.1.1.2	Population preterm newborn infants		Study	populationDescription	
261	**F.1.1.2.1**	Population number preterm newborn infants		Study	populationDescription	
262	F.1.1.3	Population newborns		Study	populationDescription	
263	**F.1.1.3.1**	Population number newborns		Study	populationDescription	
264	F.1.1.4	Population infants and toddlers		Study	populationDescription	
265	**F.1.1.4.1**	Population number infants and toddlers		Study	populationDescription	
266	F.1.1.5	Population children		Study	populationDescription	
267	**F.1.1.5.1**	Population number children		Study	populationDescription	
268	F.1.1.6	Population adolescents		Study	populationDescription	
269	**F.1.1.6.1**	Population number adolescents		Study	populationDescription	
270	F.1.2	Population adults		Study	populationDescription	
271	**F.1.2.1**	Population number adults		Study	populationDescription	
272	F.1.3	Population elderly		Study	populationDescription	
273	**F.1.3.1**	Population number elderly		Study	populationDescription	
274	F.2.1	Population male		Study	populationDescription	
275	F.2.2	Population female		Study	populationDescription	
276	F.3.1	Population healthy volunteers		InteventionalStudy	populationDescription	Inherited from Study
277	F.3.2	Population patients		Study	populationDescription	
278	F.3.3	Population specific vunerable populations	New field at 3.0.1	Study	populationDescription	
279	F.3.3.1	Population women of child bearing potential no contraception		Study	populationDescription	
280	F.3.3.2	Population women of child bearing potential contraception	New field at 3.0.1	Study	populationDescription	
281	F.3.3.3	Population pregnant women		Study	populationDescription	
282	F.3.3.4	Population nursing women		Study	populationDescription	
283	F.3.3.5	Population emergency situation		Study	populationDescription	
284	F.3.3.6	Population subjects incapable of giving consent		Study	populationDescription	
285	F.3.3.6.1	Population subjects incapable of giving consent details	If line F.3.3.6 = 'Y' then specify here	Study	populationDescription	
286	F.3.3.7	Population other subjects		Study	populationDescription	

ID	EMEA Data Requirement			BRIDG Model Element		
	Form Ref	Field Name	Comments	Class	Attribute	Comment
287	F.3.3.7.1	Population other subjects details	If line F.3.3.7 = 'Y' then specify here.	Study	populationDescription	
288	F.4.1	Population planned numbers in MS		StudySite	targetAccrualNumberRange	
289	F.4.2.1	Population planned numbers in EEA		StudySite	targetAccrualNumberRange	
290	F.4.2.2	Population planned numbers in whole trial		Study	targetAccrualNumberRange	
291	G.1.1 / G.2.1	Investigator Given Name	Field lengths are as per ICH A.3.1.3c, A.3.1.3d and A.3.1.3e Sender Identifier.	Person	name	
292	G.1.2 / G.2.2	Investigator Middle name	Field lengths are as per ICH A.3.1.3c, A.3.1.3d and A.3.1.3e Sender Identifier.	Person	name	
293	G.1.3 / G.2.3	Investigator Family Name	Field lengths are as per ICH A.3.1.3c, A.3.1.3d and A.3.1.3e Sender Identifier.	Person	name	
294	G.1.4 / G.2.4	Investigator qualifications		Person	name	
295	G.1.5 / G.2.5	Investigator Institution Name		Organization	name	
296	G.1.5 / G.2.5	Investigator Institution Department		Organization	name	
297	G.1.5.1 / G.2.5.1	Investigator Street Address	ICH A.3.1.4a (Sender Address)	Person	postalAddress	
298	G.1.5.2 / G.2.5.2	Investigator Town/City	As EV city field in DD_MAH.	Person	postalAddress	
299	G.1.5.3 / G.2.5.3	Investigator Post Code	ICH A.3.1.4d (Sender Address)	Person	postalAddress	
300	G.1.5.4 / G.2.5.4	Investigator Country	EUTCT ID of the country. Must be from the EEA/MS list only	Person	postalAddress	
301	G.1.6 / G.2.6	Investigator Telephone		Person	telcomAddress	
302	**G.1.7 / G.2.7**	Investigator Fax		Person	telcomAddress	
303	G.1.8 / G.2.8	Investigator Email		Person	telcomAddress	
304	G.3.1	CTF Organisation		Organization	name	
305	G.3.1	CTF Department		Organization	name	
306	G.3.2.1	CTF Given Name	Field lengths are as per ICH A.3.1.3c, A.3.1.3d and A.3.1.3e Sender Identifier.	Person	name	
307	G.3.2.2	CTF Middle name	Field lengths are as per ICH A.3.1.3c, A.3.1.3d and A.3.1.3e Sender Identifier.	Person	name	
308	G.3.2.3	CTF Family Name	Field lengths are as per ICH A.3.1.3c, A.3.1.3d and A.3.1.3e Sender Identifier.	Person	name	
309	G.3.3.1	CTF Street Address	ICH A.3.1.4a (Sender Address)	Person	postalAddress	
310	G.3.3.2	CTF Town/City		Person	postalAddress	
311	G.3.3.3	CTF Post Code	ICH A.3.1.4d (Sender Address)	Person	postalAddress	
312	G.3.3.4	CTF Country	EUTCT ID of the country. This can be any country in the world.	Person	postalAddress	

ID	EMEA Data Requirement			BRIDG Model Element		
	Form Ref	Field Name	Comments	Class	Attribute	Comment
313	G.3.4	CTF Telephone	ICH ICSR DTD Version 2.1 separates Tel No. (10AN), extension (5AN) Telephone country code (3AN)(ICH A.3.1.4f,g,h respectively)	Person	telcomAddress	
314	**G.3.5**	CTF Fax		Person	telecomAddress	
315	**G.3.6**	CTF Email		Person	telecomAddress	
316	G.3.7.1	CTF duties routine clinical pathology		PlannedActivity	identifer	Inherited from Activity
317	G.3.7.2	CTF duties clinical chemistry		PlannedActivity	identifer	Inherited from Activity
318	G.3.7.3	CTF duties clinical haematology		PlannedActivity	identifer	Inherited from Activity
319	G.3.7.4	CTF duties clinical microbiology		PlannedActivity	identifer	Inherited from Activity
320	G.3.7.5	CTF duties histopathology		PlannedActivity	identifer	Inherited from Activity
321	G.3.7.6	CTF duties serology endocrinology		PlannedActivity	identifer	Inherited from Activity
322	G.3.7.7	CTF duties analytical chemistry		PlannedActivity	identifer	Inherited from Activity
323	G.3.7.8	CTF duties ECG analysis		PlannedActivity	identifer	Inherited from Activity
324	G.3.7.9	CTF duties medical image analysis		PlannedActivity	identifer	Inherited from Activity
325	G.3.7.10	CTF duties endpoint test		PlannedActivity	identifer	Inherited from Activity
326	G.3.7.11	CTF duties others		PlannedActivity	identifer	Inherited from Activity
327	G.3.7.11.1	CTF duties others description		PlannedActivity	description	
328	**G.4.1**	Network Organisation		Organization	name	
329	**G.4.2.1**	Network Given Name	Field lengths are as per ICH A.3.1.3c, A.3.1.3d and A.3.1.3e Sender Identifier.	Person	name	
330	**G.4.2.2**	Network Middle Name	Field lengths are as per ICH A.3.1.3c, A.3.1.3d and A.3.1.3e Sender Identifier.	Person	name	
331	**G.4.2.3**	Network Family Name	Field lengths are as per ICH A.3.1.3c, A.3.1.3d and A.3.1.3e Sender Identifier.	Person	name	
332	**G.4.3.1**	Network Street Address	ICH A.3.1.4a (Sender Address)	Person	postalAddress	
333	**G.4.3.2**	Network Town/City		Person	postalAddress	
334	**G.4.3.3**	Network Post Code	ICH A.3.1.4d (Sender Address)	Person	postalAddress	
335	**G.4.3.4**	Network Country	EUTCT ID of the country This can be any country in the world.	Person	postalAddress	
336	**G.4.4**	Network Telephone		Person	telecomAddress	
337	**G.4.5**	Network Fax		Person	telecomAddress	
338	**G.4.6**	Network Email		Person	telecomAddress	
339	G.5.1.1	Subcontractor Organisation Name		Organization	name	
340	G.5.1.1	Subcontractor Department Name		Organization	name	
341	G.5.1.2.1	Subcontractor Given Name	Field lengths are as per ICH A.3.1.3c, A.3.1.3d and A.3.1.3e Sender Identifier.	Person	name	
342	G.5.1.2.2	Subcontractor Middle name	Field lengths are as per ICH A.3.1.3c, A.3.1.3d and A.3.1.3e Sender Identifier.	Person	name	
343	G.5.1.2.3	Subcontractor Family Name	Field lengths are as per ICH A.3.1.3c, A.3.1.3d and A.3.1.3e Sender Identifier.	Person	name	
344	G.5.1.3.1	Subcontractor Street Address	ICH A.3.1.4a (Sender Address)	Person	postalAddress	
345	G.5.1.3.2	Subcontractor Town/City		Person	postalAddress	

ID	EMEA Data Requirement			BRIDG Model Element		
	Form Ref	Field Name	Comments	Class	Attribute	Comment
346	G.5.1.3.3	Subcontractor Post Code	ICH A.3.1.4d (Sender Address)	Person	postalAddress	
347	G.5.1.3.4	Subcontractor Country	EUTCT ID of the country This can be any country in the world..	Person	postalAddress	
348	G.5.1.4	Subcontractor Telephone	ICH ICSR DTD Version 2.1 separates Tel No. (10AN), extension (5AN) Telephone country code (3AN)(ICH A.3.1.4f,g,h respectively)	Person	telecomAddress	
349	**G.5.1.5**	Subcontractor Fax		Person	telecomAddress	
350	**G.5.1.6**	Subcontractor Email		Person	telecomAddress	
351	G.5.1.7	Subcontractor duties all sponsor tasks	(Y/N) There will be 10 options with selection buttons and the option of 'Other'	PlannedActivity	identifer	Inherited from Activity
352	G.5.1.8	Subcontractor duties monitoring		PlannedActivity	identifer	Inherited from Activity
353	G.5.1.9	Subcontractor duties regulatory		PlannedActivity	identifer	Inherited from Activity
354	G.5.1.10	Subcontractor duties investigator recruitment		PlannedActivity	identifer	Inherited from Activity
355	G.5.1.11	Subcontractor duties IVRS treatment		PlannedActivity	identifer	Inherited from Activity
356	G.5.1.12	Subcontractor duties data management		PlannedActivity	identifer	Inherited from Activity
357	G.5.1.13	Subcontractor duties edata capture		PlannedActivity	identifer	Inherited from Activity
358	G.5.1.14	Subcontractor duties SUSAR reporting		PlannedActivity	identifer	Inherited from Activity
359	G.5.1.15	Subcontractor duties quality assurance auditing		PlannedActivity	identifer	Inherited from Activity
360	G.5.1.16	Subcontractor duties statistical analysis	Y/N New field at 3.0.1	PlannedActivity	identifer	Inherited from Activity
361	G.5.1.17	Subcontractor duties medical writing		PlannedActivity	identifer	Inherited from Activity
362	G.5.1.18	Subcontractor duties others		PlannedActivity	identifer	Inherited from Activity
363	G.5.1.18.1	Subcontractor duties others description		PlannedActivity	identifer	Inherited from Activity
364	H.2.1	NCA Organisation		Organization	name	
365	H.2.2.1	NCA Street Address	ICH A.3.1.4a (Sender Address)	Organization	postalAddress	
366	H.2.2.1	NCA Town/City	Town/city only. No detailed address. As EV city field in DD_MAH.	Organization	postalAddress	
367	H.2.2.1	NCA Post Code	ICH A.3.1.4d (Sender Address)	Organization	postalAddress	
368	H.2.2.1	NCA Country	EUTCT ID of the country. Must be from the EEA/MS list only	Organization	postalAddress	
369	H.2.3	NCA Submission date		Submission	receiptDate	
370	H.2.1	IEC Organisation		Organization	name	
371	H.2.2.1	IEC Street Address	ICH A.3.1.4a (Sender Address)	Organization	postalAddress	
372	H.2.2.1	IEC Town/City	Town/city only. No detailed address. As EV city field in DD_MAH.	Organization	postalAddress	
373	H.2.2.1	IEC Post Code	ICH A.3.1.4d (Sender Address)	Organization	postalAddress	
374	H.2.2.1	IEC Country	EUTCT ID of the country Must be from the EEA/MS list only	Organization	postalAddress	
375	H.2.3	IEC Submission date	yyyymmdd	Submission	receiptDate	

ID	EMEA Data Requirement			BRIDG Model Element		
	Form Ref	Field Name	Comments	Class	Attribute	Comment
376	H.3.1 / H.3.2 / H.3.3	IEC Opinion Status	Drop-down list.	RegulatoryAssessment	statusCode	Proposed addition to BRIDG
377	H.3.3.1	IEC Opinion date	yyyymmdd	RegulatoryAssessment	assessmentDate	
378	H.3.3.2 / H.3.3.3	IEC Opinion Given		RegulatoryAssessment	assessmentCode	
379	H.3.3.3.1	IEC Opinion not favourable reasons		RegulatoryAssessment	assessmentReasonCode	Proposed addition to BRIDG

ID	BRIDG Model Element			CT.GOV Data Requirement	
	Class	Attribute	Comment	Data Item	Comment
1	Activity	identifier		Human Subjects Review Board Approval Number	Number assigned by the human subjects review board upon approval of the protocol. May be ommitted if status is anything other than approved. If the human subjects review board does not assign numbers, please enter the date of approval in mm/dd/yyyy format. (required only if status is "Submitted, approved")
2	Arm	description		Arm Description (note: above data element definition incorrect?) (aka Group/cohort Description)	Brief description of the arm. This element may not be necessary if the associated intervention descriptions contain sufficient information to describe the arm.
3	Arm	name		Arm Label (aka Group/Cohort Label)	The short name used to identify the arm. Examples: - Metformin - Lifestyle counseling - Sugar pill
4	Arm	typeCode		Arm Type	Select one - Experimental - Active Comparator - Placebo Comparator - Sham Comparator - No intervention - Other
5	Arm	typeCode		Arms/Groups (intended to reflect the intervention assignment to the arm)	If arms or groups have been specified for the protocol, select the ones for which the intervention is to be administered. For interventional studies with arms specified, all arms must have at least one intervention (unless arm type is "No Intervention") and each intervention must be assigned to at least one arm. For observational studies with groups specified, each intervention (if any) must be assigned to at least one group.
6	DefinedSubstanceAdministration	doseRegimen		Intervention Description	Comparator dosage/regimen info
7	DefinedSubstanceAdministration	doseRegimen		Intervention Description	Amount of dose administered as part of the study regimen
8	DefinedSubstanceAdministration	routeOfAdministrationCode		Intervention Description	The route by which the product is administered.
9	DefinedSubstanceAdministration	routeOfAdministrationCode		Intervention Description	Method used to administer the study drug to the subject.
10	Document	keywordText		Keywords	Words or phrases that best describe the protocol. Keywords help users find studies in the database. Use NLM's Medical Subject Heading (MeSH) controlled vocabulary terms where appropriate. Be as specific and precise as possible. Avoid acronyms and abbreviations.

ID	BRIDG Model Element			CT.GOV Data Requirement	
	Class	Attribute	Comment	Data Item	Comment
11	Document	officialTitle		Official Title	Definition: Official name of the protocol provided by the study principal investigator or sponsor. Example: Phase 1 Study of Recombinant Vaccinia Virus That Expresses Prostate Specific Antigen in Metastatic Adenocarcinoma of the Prostate
12	DocumentIdentifier	identifier		ID Source	The organization assigning the protocol identifier. NOTE: There may be multiple numbers (Nat'l number, coop group number). [PRG, eudraCT]
13	DocumentIdentifier	identifier		Organization's Unique Protocol ID Secondary IDs	Unique identification assigned to the protocol by the sponsoring organization, usually an accession number or a variation of a grant number. Multiple studies conducted under the same grant must each have a unique number. Examples: ABT-1233-RV Merck-023 ACTG 021
14	DocumentIdentifier	identifier		Organization's Unique Protocol ID Secondary IDs	Protocol Identifying Number: Any of one or more unique codes that refers to a specific protocol. NOTE: There may be multiple numbers (Nat'l number, coop group number). [PRG; eudraCT] Other identifying numbers and issuing authorities besides the Primary Registry, if any. Include the sponsor name and sponsor-issued trial number (e.g., protocol number) if available. Also include other trial registries that have issued an identifying number to this trial. There is no limit on the number of Secondary identifying numbers that can be provided. (WHO)
15	DocumentIdentifier	identifier		Secondary IDs	Other identification numbers assigned to the protocol, including unique identifiers from other registries and NIH grant numbers, if applicable. Provide up to 5 Secondary ID Numbers, one per line. Examples: ISRCTN12345678 NCI-793-0115D R01-123456-1
16	DocumentIdentifier	typeCode		ID Type	Identify kind of ID -- eg NIH Grant, Funding, Registry, Other

ID	BRIDG Model Element			CT.GOV Data Requirement	
	Class	Attribute	Comment	Data Item	Comment
17	InterventionalStudy	acceptsHealthyVolunteersIndicator		Accepts on Healthy Volunteers?	Indicate if persons who have not had the condition(s) being studied or otherwise related conditions or symptoms, as specified in the eligibility requirements, may participate in the study. Select Yes/No.
18	InterventionalStudy	allocationCode		Allocation	Participant assignment to intervention group (at least one of the following required: Intervention Model, Masking, Allocation. All may be required as part of Study Design under PL 110-85, Section 801) - N/A: single arm study - Randomized Controlled Trial: participants are assigned to intervention groups by chance - Nonrandomized Trial: participants are expressly assigned to intervention groups through a nonrandom method, such as physician choice.
19	InterventionalStudy	blindingSchemaCode		Masking	Knowledge of intervention assignments (at least one of the following required: Intervention Model, Masking, Allocation. All may be required as part of Study Design under PL 110-85, Section 801) - Open: no masking is used. All involved know the identity of the intervention assignment. - Single Blind: one party, either the investigator or participant, is unaware of the intervention assignment; also called single-masked study. - Double Blind: two or more parties are unaware of the intervention assignment If Single Blind or Double Blind is selected, check the role(s) that are to be masked: Subject, Caregiver, Investigator or Outcomes Assessor.
20	InterventionalStudy	controlConcurrencyTypeCode		Time Perspective (Observational Studies only, and the fit to the PRG definition isn't perfect)	A code specifying the temporal relationship of the control to the study intervention. For example, concurrent, historical, pre/post (patient owned control).

ID	BRIDG Model Element			CT.GOV Data Requirement	
	Class	Attribute	Comment	Data Item	Comment
21	InterventionalStudy	interventionDescription		Intervention Description	Cover key details of the intervention. Must be sufficiently detailed to distinguish between arms of a study (e.g., comparison of different dosages of drug) and/or among similar interventions (e.g., comparison of multiple implantable cardiac defibrillators). For example, interventions involving drugs may include dosage form, dosage, frequency and duration
22	Material	name		Biospecimen Description	Specify all types of biospecimens to be retained (e.g., whole blood, serum, white cells, urine, tissue).
23	ObservationalStudy	samplingMethodCode		Sampling Method	For observational studies only, select one and explain in Detailed Description. - Probability Sample: exclusively random process to guarantee that each participant or population has specified chance of selection, such as simple random sampling, systematic sampling, stratified random sampling, cluster sampling, and consecutive patient sampling - Non-Probability Sample: any of a variety of other sampling processes, such as convenience sampling or invitation to volunteer
24	ObservationalStudy	timePerspectiveCode		Observational Time Perspective	Temporal relationship of observation period to time of subject enrollment. Select one. - Prospective: look forward using periodic observations collected predominantly following subject enrollment - Retrospective: look back using observations collected predominantly prior to subject selection and enrollment - Cross-sectional: observations or measurements made at a single point in time, usually at subject enrollment - Other - explain in Detailed Description
25	Organization	name		Collaborators	Other organizations (if any) providing support, including funding, design, implementation, data analysis and reporting. The data provider is responsible for confirming all collaborators before listing them. Provide up to 10 full names of collaborating organizations.
26	Organization	name		Collaborators	Person is not defined in CT.gov
27	Organization	name		Collaborators includes funding sponsors	Funding Organization
28	Organization	name		Collaborators includes funding sponsors	Funding Person

ID	BRIDG Model Element			CT.GOV Data Requirement	
	Class	Attribute	Comment	Data Item	Comment
29	Organization	name		Data Monitoring Committee?	Indicate whether a data monitoring committee has been appointed for this study. The data monitoring committee (board) is a group of independent scientists who are appointed to monitor the safety and scientific integrity of a human research intervention, and to make recommendations to the sponsor regarding the stopping of the trial for efficacy, for harms or for futility. The composition of the committee is dependent upon the scientific skills and knowledge required for monitoring the particular study.
30	Organization	name		FDA Regulated Intervention?	Indicate whether this trial includes an intervention subject to US Food and Drug Administration regulation under section 351 of the Public Health Service Act or any of the following sections of the Federal Food, Drug and Cosmetic Act: 505, 510(k), 515, 520(m), and 522. Select Yes/No.
31	Organization	name		Human Subjects Review Board Affiliation	Institutional Review Board Name, Affiliation and Contact Information
32	Organization	name		Human Subjects Review Board Name, Affiliation and Contact	Institutional Review Board Name, Affiliation and Contact Information
33	Organization	name		Overall Study Officials: Organizational Affiliation	Full name of the official's organization. If none, specify Unaffiliated. Organization Affiliation
34	Organization	name		Oversight Authorities	The name of each national or international health organization with authority over the protocol. Use the following format for each authority: country: organization name Examples: United States: Institutional Review Board United States: Food and Drug Administration Germany: Federal Institute for Drugs and Medical Devices Australia: Therapeutic Goods Administration
35	Organization	name		Oversight Authorities	The name of each national or international health organization with authority over the protocol.
36	Organization	name		Protocol Location.Facility	Name: Full name of the organization where the protocol is being conducted
37	Organization	name		Responsible Party Organization	the sponsor or the principal investigator's organizational affiliation

ID	BRIDG Model Element			CT.GOV Data Requirement	
	Class	Attribute	Comment	Data Item	Comment
38	Organization	name		Sponsor	Name of primary organization that oversees implementation of study and is responsible for data analysis. For applicable clinical trials, sponsor is defined in 21 CFR 50.3. Examples: National Institute of Allergy and Infectious Diseases, Bristol-Myers Squibb
39	Organization	name		Sponsor	The individual, organization, group or other legal entity which takes responsibility for initiating, managing and/or financing a study. The Primary Sponsor is responsible for ensuring that the ensuring that the trial is properly registered. The Primary Sponsor may or may not be the main funder.
40	Person	name		Backup Central Contact: Degree	Degree
41	Person	name		Backup Central Contact: Name (first, middle int, last)	First Name, Middle Initial, Last Name
42	Person	name		Backup Facility Contact: Degree	Degree
43	Person	name		Backup Facility Contact: Name (first, middle int, last)	First Name, Middle Initial, Last Name
44	Person	name		Central Contact	Email address, telephone number, or postal address of the contact who will respond to general queries, including information about current recruitment status.
45	Person	name		Investigators (at the protocol location)	An investigator assigned the responsibility for the coordination of investigators at different centers participating in a multicenter trial. [ICH E6]
46	Person	name		Investigators (at the protocol location)	A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator. [ICH] 21 CFR 50.3 expands on the ICH definition by stating that the investigator is the individual "under whose immediate direction the test article is administered or dispensed to, or used involving, a subject, or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team."
47	Person	name		Investigators: Degree	Degree
48	Person	name		Investigators: Name (first, middle int, last)	First Name, Middle Initial, Last Name

ID	BRIDG Model Element			CT.GOV Data Requirement	
	Class	Attribute	Comment	Data Item	Comment
49	Person	name		Overall Study Officials	A person identified when the study is approved as the person responsible for the overall conduct of the clinical trial.
50	Person	name		Overall Study Officials	Person(s) responsible for the overall scientific leadership of the protocol, including study principal. First Name, Middle Initial, Last Name investigator.
51	Person	name		Overall Study Officials	Position or function of the official. Study Chair/Study Director/Study Principal Investigator
52	Person	name		Overall Study Officials: Degree	Degree
53	Person	name		Primary Central Contact: Degree	Degree
54	Person	name		Primary Central Contact: Name (first, middle int, last)	Person providing centralized, coordinated recruitment information for the entire study. First Name, Middle Initial, Last Name
55	Person	name		Primary Facility Contact: Degree	Degree
56	Person	name		Primary Facility Contact: Name (first, middle int, last)	First Name, Middle Initial, Last Name
57	Person	name		Responsible Party Name	Name/Official Title - for either the principal investigator or sponsor contact. As defined in US Public Law 110-85, Title VIII, Section 801, the term "responsible party", with respect to a clinical trial, means the sponsor of the clinical trial (as defined in 21 CFR 50.3) or the principal investigator of such clinical trial if so designated by a sponsor, grantee, contractor, or awardee, so long as the principal investigator is responsible for conducting the trial, has access to and control over the data from the clinical trial, has the right to publish the results of the trial, and has the ability to meet all of the requirements for the submission of clinical trial information.

ID	BRIDG Model Element			CT.GOV Data Requirement	
	Class	Attribute	Comment	Data Item	Comment
58	Person	name		Responsible Party Title	Name/Official Title - for either the principal investigator or sponsor contact. As defined in US Public Law 110-85, Title VIII, Section 801, the term "responsible party", with respect to a clinical trial, means the sponsor of the clinical trial (as defined in 21 CFR 50.3) or the principal investigator of such clinical trial if so designated by a sponsor, grantee, contractor, or awardee, so long as the principal investigator is responsible for conducting the trial, has access to and control over the data from the clinical trial, has the right to publish the results of the trial, and has the ability to meet all of the requirements for the submission of clinical trial information.
59	Person	telecomAddress		Backup Central Contact: Information (phone, e-mail)	Phone number of the Office phone of the facility contact person. Use the format 123-456-7890 within the United States and Canada. Otherwise, provide the country code. Ext: phone extension, if needed. Email: Electronic mail address of the facility contact person.
60	Person	telecomAddress		Backup Facility Contact: Information (phone, e-mail)	Phone number of the Office phone of the facility contact person. Use the format 123-456-7890 within the United States and Canada. Otherwise, provide the country code. Ext: phone extension, if needed. Email: Electronic mail address of the facility contact person.
61	Person	telecomAddress		Primary Central Contact: Information (phone, e-mail)	Phone number of the Office phone of the facility contact person. Use the format 123-456-7890 within the United States and Canada. Otherwise, provide the country code. Ext: phone extension, if needed. Email: Electronic mail address of the facility contact person.
62	Person	telecomAddress		Primary Facility Contact: Information (phone, e-mail)	Phone number of the Office phone of the facility contact person. Use the format 123-456-7890 within the United States and Canada. Otherwise, provide the country code. Ext: phone extension, if needed. Email: Electronic mail address of the facility contact person.
63	Person	telecomAddress		Responsible Party Email	provide telephone number and/or email address [required for internal administrative use only; not revealed to public]

ID	BRIDG Model Element			CT.GOV Data Requirement	
	Class	Attribute	Comment	Data Item	Comment
64	Person	telecomAddress		Responsible Party Telephone	provide telephone number and/or email address [required for internal administrative use only; not revealed to public]
65	PlannedContingentOnRelationship	evaluableExpression	Proposed addition to BRIDG	Gender	Physical gender of individuals who may participate in the protocol. Select one. - Both: both female and male participants are being studied - Female: only female participants are being studied - Male: only male participants are being studied
66	PlannedContingentOnRelationship	evaluableExpression	Proposed addition to BRIDG	Maximum Age	Maximum age of participants. Provide a number and a unit of time (years, months, weeks, days, hours or minutes). Select "N/A (No limit)" if no maximum age is indicated.
67	PlannedContingentOnRelationship	evaluableExpression	Proposed addition to BRIDG	Minimum Age	Minimum age of participants. Provide a number and select a unit of time (years, months, weeks, days, hours or minutes). Select "N/A (No limit)" if no minimum age is indicated.
68	Product	nameCode		Intervention Name	For drugs use generic name; for other types of interventions provide a brief descriptive name. For investigational new drugs that do not yet have a generic name, a chemical name, company code or serial number may be used on a temporary basis. As soon as the generic name has been established, update the associated protocol records accordingly. For non-drug intervention types, provide an intervention name with sufficient detail so that it can be distinguished from other similar interventions.
69	Product	nameCode		Other Names	List other names used to identify the intervention, past or present (e.g., brand name for a drug). These names will be used to improve search results in ClinicalTrials.gov.
70	RegulatoryApplication	identifier		IND/IDE Number	Number assigned to an Investigational New Drug Application (IND) or Investigational Device Exemption (IDE). (Will not be made public - for administrative purposes only.) Examples: 22,333; BB1234
71	RegulatoryApplication	typeCode		CT.gov	Indicator of IND/IDE

ID	BRIDG Model Element			CT.GOV Data Requirement	
	Class	Attribute	Comment	Data Item	Comment
72	RegulatoryApplication	typeCode		CT.gov	Indicate if the protocol involves an Investigational New Drug Application (IND) or Investigational Device Exemption (IDE) under US Food and Drug Administration regulations (Will not be made public - for administrative purposes only.) The valid values are Yes or No.
73	RegulatoryAuthority	juridictionCode		IND/IDE Grantor	FDA center to which the IND or IDE was submitted, i.e., Center for Drug Evaluation and Research (CDER) or Center for Biologics Evaluation and Research (CBER) for INDs; Center for Devices and Radiological Health (CDRH) for IDEs. Select one. (Will not be made public - for administrative purposes only.)
74	Study	~ derived based on specialization type		Study Type	Definition: Nature of the investigation. Select one. Interventional: studies in human beings in which individuals are assigned by an investigator based on a protocol to receive specific interventions. Subjects may receive diagnostic, therapeutic or other types of interventions. The assignment of the intervention may or may not be random. The individuals are then followed and biomedical and/or health outcomes are assessed. Observational: studies in human beings in which biomedical and/or health outcomes are assessed in pre-defined groups of individuals. Subjects in the study may receive diagnostic, therapeutic, or other interventions, but the investigator does not assign specific interventions to the subjects of the study. Expanded Access: records describing the procedure for obtaining an experimental drug or device for patients who are not adequately treated by existing therapy, who do not meet the eligibility criteria for enrollment, or who are otherwise unable to participate in a controlled clinical

ID	BRIDG Model Element			CT.GOV Data Requirement	
	Class	Attribute	Comment	Data Item	Comment
75	Study	acronym		Acronym	Definition: Acronym or initials used to identify this study, if applicable. Enter only the acronym. If supplied, the acronym is automatically displayed in parentheses following the brief title. Example: Brief Title: Women's Health Initiative Acronym: WHI Displayed on ClinicalTrials.gov as: Women's Health Initiative (WHI)
76	Study	designConfigurationCode		Intervention Model	Clinical trial design developed to compare treatment groups in a clinical trial. NOTE: The configuration usually requires randomization to one or more treatment arms, each arm being allocated a different (or no) treatment. Examples include: Parallel Group Design, Crossover Design, Factorial Designs. [from ICH E9]
77	Study	designConfigurationCode		Study Design-Intervention Model	Plan for the precise procedure to be followed in a clinical trial, including planned and actual timing of events, choice of control group, method of allocating treatments, blinding methods; assigns a subject to pass through one or more epochs in the course of a trial. Specific design elements, e.g., crossover, parallel; dose-escalation [Modified from Pocock, Clinical Trials: A Practical Approach] See Trial Design Model. See also, arm, epoch, and visit.
78	Study	phaseCode		Study Phase	Phase of investigation, as defined by the US FDA for trials involving investigational new drugs. (N/A, Phase 0, Phase 1, Phase 1/Phase2, Phase 2, Phase 2/Phase 3, Phase 3, Phase 4)
79	Study	plannedStudySubjectExperience		Expanded Access Status	Indicate whether any non-protocol access is to be provided for the investigational drug or device. If so, an Expanded Access record should also be created for this IND/IDE. The valid values are Yes or No.

ID	BRIDG Model Element			CT.GOV Data Requirement	
	Class	Attribute	Comment	Data Item	Comment
80	Study	plannedStudySubjectExperience		Expanded Access Status	Status indicating availability of an experimental drug or device outside any clinical trial protocol. This data element is only applicable for Expanded Access records (see Expanded Access under Study Type). Select one. - Available: expanded access is currently available for this treatment. - No longer available: expanded access was available for this treatment previously but is not currently available and will not be available in the future. - Temporarily not available: expanded access is not currently available for this treatment, but is expected to be available in the future. - Approved for marketing: this treatment has been approved for sale to the public.
81	Study	plannedStudySubjectExperience		Number of Arms (aka "Number of Groups/cohorts")	Number of intervention groups (enter 1 for single-arm study).
82	Study	populationDescription		Eligibility Criteria/Study population description	Summary criteria for participant selection. The preferred format includes lists of inclusion and exclusion criteria as shown below. Example: Inclusion Criteria: - Clinical diagnosis of Alzheimer's Disease - Must be able to swallow tablets Exclusion Criteria: - Insulin dependent diabetes - Thyroid disease
83	Study	primaryPurposeCode		Intervention Type	Select one per intervention - Drug (including placebo) - Device (including sham) - Biological/Vaccine - Procedure/Surgery - Radiation - Behavioral (e.g., Psychotherapy, Lifestyle Counseling) - Genetic (including gene transfer, stem cell and recombinant DNA) - Dietary Supplement (e.g., vitamins, minerals) - Other

ID	BRIDG Model Element			CT.GOV Data Requirement	
	Class	Attribute	Comment	Data Item	Comment
84	Study	primaryPurposeCode		Primary Purpose (code list)	Reason for the protocol - Treatment: protocol designed to evaluate one or more interventions for treating a disease, syndrome or condition - Prevention: protocol designed to assess one or more interventions aimed at preventing the development of a specific disease or health condition - Diagnostic: protocol designed to evaluate one or more interventions aimed at identifying a disease or health condition - Supportive Care: protocol designed to evaluate one or more interventions where the primary intent is to maximize comfort, minimize side effects or mitigate against a decline in the subject's health or function. In general, supportive care interventions are not intended to cure a disease. - Screening: protocol designed to assess or examine methods of identifying a condition (or risk factors for a condition) in people who are not yet known to have the condition (or risk factor). - Health Services Research: protocol designed to evaluate the delivery, processes, management,
85	Study	purposeStatement		Brief Summary (note: Trial Purpose & Objective on "other" worksheet)	Short description of the protocol intended for the lay public. Include a brief statement of the study hypothesis.
86	Study	purposeStatement		Detailed Description (suggest changing "detailed description" on CT.gov sheet to "Brief summary")	A statement describing the overall rationale of the study. This field describes the contribution of this study to product development, i.e., what knowledge is being contributed from the conduct of this study. Note: This differs from StudyObjective describes what the study hopes to accomplish whereas the purposeStatement is the reason why the study is being conducted.
87	Study	targetAccrualNumberRange		Enrollment (Target or Actual Number of Subjects)	Number of subjects in the trial. A "Type" menu is also included, with options Anticipated and Actual. For active studies, set Type to Anticipated and specify the expected enrollment, updating the number as needed over the course of the study. Upon study completion, change Type to Actual and update the enrollment if necessary.

ID	BRIDG Model Element			CT.GOV Data Requirement	
	Class	Attribute	Comment	Data Item	Comment
88	Study	populationDescription		Study Population Description (applies to Observational)	For observational studies only, a description of the population from which the groups or cohorts will be selected (e.g., primary care clinic, community sample, residents of a certain town).
89	StudyAgent	functionCode		Biospecimen Retention	- None Retained - no samples Retained - samples With DNA - samples Retained, With potential for extraction of DNA from at least one of the types of samples Retained (e.g., frozen tissue, whole blood) - samples Without DNA - samples Retained, With no potential for DNA extraction from any Retained samples (e.g., fixed tissue, plasma)
90	StudyColleague	roleCode		Central Contact: Role (Primary or Backup)	Primary or Backup
91	StudyColleague	roleCode		Facility Contact: Role (Primary or Backup)	Primary or Backup
92	StudyColleague	roleCode		Investigators: Role (principle or sub investigator)	Primary or Sub Investigator
93	StudyObjective	description		Detailed description	The reason for performing a trial in terms of the scientific questions to be answered by the analysis of data collected during the trial. NOTE: The primary objective is the main question to be answered and drives any statistical planning for the trial (e.g., calculation of the sample size to provide the appropriate power for statistical testing). Secondary objectives are goals of a trial that will provide further information on the use of the treatment.
94	StudyOutcomeMeasure	name		Study Design-Primary and Secondary Outcome Measures	Measure
95	StudyOutcomeMeasure	name		Study Design-Primary and Secondary Outcome Measures	Primary or Secondary?
96	StudyOutcomeMeasure	name		Study Design-Primary and Secondary Outcome Measures	Time Frame
97	StudyOutcomeMeasure	primaryIndicator		Study Design-Primary and Secondary Outcome Measures: Primary or Secondary??	Primary or Secondary?
98	StudyOutcomeMeasure	typeCode		Safety Issue	An indication that the outcome measure for the study is safety related.

ID	BRIDG Model Element			CT.GOV Data Requirement	
	Class	Attribute	Comment	Data Item	Comment
99	StudyOutcomeMeasure	typeCode		Study Classification	Type of primary outcome or endpoint that the protocol is designed to evaluate. Select one. - N/A: not applicable - Safety: show if the drug is safe under conditions of proposed use - Efficacy: measure of an intervention's influence on a disease or health condition - Safety/Efficacy - Bio-equivalence: scientific basis for comparing generic and brand name drugs - Bio-availability: rate and extent to which a drug is absorbed or otherwise available to the treatment site in the body - Pharmacokinetics: the action of a drug in the body over a period of time including the process of absorption, distribution and localization in tissue, biotransformation, and excretion of the compound - Pharmacodynamics: action of drugs in living systems - Pharmacokinetics/dynamics
100	StudyOverallStatus	anticipatedIndicator		Primary Completion Date Type	A "Type" menu is also included, with options Anticipated and Actual. For active studies, set Type to Anticipated and specify the expected completion date, updating the date as needed over the course of the study. Upon study completion, change Type to Actual and update the date if necessary.
101	StudyOverallStatus	anticipatedIndicator		Primary Completion Date	As specified in US Public Law 110-85, Title VIII, Section 801, with respect to an applicable clinical trial, the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the prespecified protocol or was terminated. A "Type" menu is also included, with options Anticipated and Actual. For active studies, set Type to Anticipated and specify the expected completion date, updating the date as needed over the course of the study. Upon study completion, change Type to Actual and update the date if

ID	BRIDG Model Element			CT.GOV Data Requirement	
	Class	Attribute	Comment	Data Item	Comment
102	StudyOverallStatus	statusCode		Human Subjects Review Board Approval Status	Human subjects review board approval status. Select one. - Request not yet submitted: review board approval is required but has not yet been requested - Submitted, pending: review board approval has been requested but not yet granted - Submitted, approved: review board approval has been requested and obtained - Submitted, exempt: review board has granted an exemption in response to the approval request - Submitted, denied: review board has denied the approval request - Submission not required: the study does not require human subjects review
103	StudyOverallStatus	statusCode		Overall Recruitment Status	Overall accrual activity for the protocol. Select one. Not yet recruiting: participants are not yet being recruited Recruiting: participants are currently being recruited Enrolling by invitation: participants are being (or will be) selected from a predetermined population Active, not recruiting: study is ongoing (i.e., patients are being treated or examined), but participants are not currently being recruited or enrolled Completed: the study has concluded normally; participants are no longer being examined or treated (i.e., last patient's last visit has occurred) Suspended: recruiting or enrolling participants has halted prematurely but potentially will resume Terminated: recruiting or enrolling participants has halted prematurely and will not resume; participants are no longer being examined or treated Withdrawn: study halted prematurely, prior to enrollment of first participant
104	StudyOverallStatus	statusDate		Primary Completion Date	As specified in US Public Law 110-85, Title VIII, Section 801, with respect to an applicable clinical trial, the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the prespecified protocol or was terminated.

ID	BRIDG Model Element			CT.GOV Data Requirement	
	Class	Attribute	Comment	Data Item	Comment
105	StudyOverallStatus	statusDate		Record Verification Date	Date the protocol information was last verified. Verification date is shown along with organization name on ClinicalTrials.gov to indicate to the public whether the information is being kept current, particularly recruiting status and contact information. Update verification date when reviewing the record for accuracy and completeness, even if no other changes are made.
106	StudyOverallStatus	statusDate		Study Completion Date	Final date on which data was (or is expected to be) collected. Use the Type menu (Anticipated/Actual) as described above.
107	StudyOverallStatus	statusDate		Study Start Date	Date that enrollment to the protocol begins.
108	StudyOverallStatus	studyStoppedReasonCode		Why Study Stopped? Intended to represent the brief description (note: overall recruitment status would indicate terminated, w/d, suspended)	For suspended, terminated or withdrawn studies, provide a brief explanation of why the study has been halted or terminated. If desired, use brief summary or detailed description to provide additional information.
109	StudyProtocolDocument	publicDescription		Delayed Posting?	If this is a Section 801 applicable clinical trial, indicate whether this trial includes a device NOT previously approved or cleared by the US FDA for any use, as specified in US Public Law 110-85, Title VIII, Section 801. Select Yes/No. If "Yes" is selected, full posting of the trial information on ClinicalTrials.gov will be delayed until after the device has been approved or cleared. At that time, it is the registrant's responsibility to change this selection to "No" and release the record for full publication.
110	StudyProtocolDocument	publicDescription		Detailed Description	Extended description of the protocol, including more technical information (as compared to the Brief Summary) if desired. Do not include the entire protocol; do not duplicate information recorded in other data elements, such as eligibility criteria or outcome measures.

ID	BRIDG Model Element			CT.GOV Data Requirement	
	Class	Attribute	Comment	Data Item	Comment
111	StudyProtocolDocument	publicDescription		Section 801?	If this trial includes an FDA regulated intervention, indicate whether this is an "applicable clinical trial" as defined in US Public Law 110-85, Title VIII, Section 801. Briefly, applicable drug trials include controlled clinical investigations, other than Phase I investigations, of a drug or biologic subject to US FDA regulation. Applicable device clinical trials are controlled trials with health outcomes of devices subject to FDA regulation, other than small feasibility studies, and pediatric postmarket surveillance. Select Yes/No.
112	StudyProtocolDocument	publicTitle		Brief Title	Definition: Protocol title intended for the lay public. Example: Safety Study of Recombinant Vaccinia Virus Vaccine to Treat Prostate Cancer
113	StudyRecruitmentStatus	statusCode		Overall Recruitment Status	StudyRecruitmentStatus: Status of finding and enrolling appropriate subjects (those selected on the basis of the protocol's inclusion and exclusion criteria) into a clinical study. StudyOverallStatus: Describes the comprehensive state of the study
114	StudyReference	citationDescription		Citation	Bibliographic reference in NLM's MEDLINE format. Example: Barza M; Pavan PR; Doft BH; Wisniewski SR; Wilson LA; Han DP; Kelsey SF. Evaluation of microbiological diagnostic techniques in postoperative endophthalmitis in the Endophthalmitis Vitrectomy Study. Arch Ophthalmol 1997 Sep;115(9):1142-50
115	StudyReference	publicationIdentifier		MEDLINE Identifier	Unique PubMed Identifier (PMID) for the citation in MEDLINE. Example: PMID: 10987815
116	StudyReference	publicationIdentifier		Note: CTGOV has "Citatons" which are categorized by "Results" vs "Other" -- the citation words in the CT.gov elements suggest those are already "results". If you know it is a result than you don't need the flag else you need this flag	An indication that the published results citation related to the current study.
117	StudyReference	publicationIdentifier		Results Reference?	Indicate if the reference provided reports on results from this clinical research study.
118	StudyReference	publicationName		References	Citations to publications related to the protocol: background and/or results. Provide either the unique PubMed Identifier (PMID) of an article or enter the full bibliographic citation.

ID	BRIDG Model Element			CT.GOV Data Requirement	
	Class	Attribute	Comment	Data Item	Comment
119	StudyReference	universalResourceLocator		URL	A Web site directly relevant to the protocol may be entered, if desired. Do not include sites whose primary goal is to advertise or sell commercial products or services. Complete URL, including http:// Example: http://www.alzheimers.org/
120	StudyReference	universalResourceLocator		URL Description	Title or brief description of the linked page. If the page being linked is the protocol's home page on the sponsor's Web site, include the words "Click here for more information about this study:" and provide the name of the protocol. Examples: Click here for more information about this study: Clinical Trial of Eye Prophylaxis in the Newborn The Alzheimer's Disease Education and Referral (ADEAR) Center is a service of the National Institute on Aging
121	StudySite	accrualStatusCode		Facility Recruitment Status (using a code list)	Protocol accrual activity at a facility. Select one. - Not yet recruiting: participants are not yet being recruited - Recruiting: participants are currently being recruited - Enrolling by invitation: participants are being (or will be) selected from a predetermined population - Active, not recruiting: study is ongoing (i.e., patients are being treated or examined), but participants are not currently being recruited or enrolled - Completed: the study has concluded normally; participants are no longer being examined or treated (i.e., last patient's last visit has occurred) - Suspended: recruiting or enrolling participants has halted prematurely but potentially will resume - Terminated: recruiting or enrolling participants has halted prematurely and will not resume; participants are no longer being examined or treated - Withdrawn: study halted prematurely, prior to enrollment of first participant
122	StudySiteContact	postalAddress		Protocol Location: Partial Address (Facility City, State, Postal Code, Country)	Partial Address of Facility Location: City, State/Province, Postal Code, Country

ID	BRIDG Model Element			WHO.CTR Data Requirements	
	Class	Attribute	Comment	Data Item	Comment
1	DefinedSubstanceAdministration	doseRegimen		Intervention	Amount of dose administered as part of the study regimen
2	DefinedSubstanceAdministration	routeOfAdministrationCode		Intervention	Method used to administer the study drug to the subject.
3	Document	officialTitle		Scientific Title - Scientific title of the study as it appears in the protocol submitted for funding and ethical review. Include trial acronym if available. (WHO CTR Item 10)	Definition: Official name of the protocol provided by the study principal investigator or sponsor. Example: Phase 1 Study of Recombinant Vaccinia Virus That Expresses Prostate Specific Antigen in Metastatic Adenocarcinoma of the Prostate
4	DocumentIdentifier	identifier		Primary register (ASSIGNED ID NUMBER by the Registry) and Registry ID number (WHO CTR Item 1)	A unique identification given to a protocol by a registry.
5	DocumentIdentifier	identifier		Secondary Identifying Numbers (WHO CTR Item 3)	Protocol Identifying Number: Any of one or more unique codes that refers to a specific protocol. NOTE: There may be multiple numbers (Nat'l number, coop group number). [PRG; eudraCT] Other identifying numbers and issuing authorities besides the Primary Registry, if any. Include the sponsor name and sponsor-issued trial number (e.g., protocol number) if available. Also include other trial registries that have issued an identifying number to this trial. There is no limit on the number of Secondary identifying numbers that can be provided. (WHO)
6	InterventionalStudy	allocationCode		Allocation	Participant assignment to intervention group (at least one of the following required: Intervention Model, Masking, Allocation. All may be required as part of Study Design under PL 110-85, Section 801) - N/A: single arm study - Randomized Controlled Trial: participants are assigned to intervention groups by chance - Nonrandomized Trial: participants are expressly assigned to intervention groups through a nonrandom method, such as physician choice

ID	BRIDG Model Element			WHO.CTR Data Requirements	
	Class	Attribute	Comment	Data Item	Comment
7	InterventionalStudy	blindedRoleCode		Study Type - Who is blinded	Registries may collect data on who is masked (the subjects, therapist or clinician, assessor or data analyst) If Single Blind or Double Blind is selected, check the role(s) that are to be masked: Subject, Caregiver, Investigator or Outcomes Assessor.
8	InterventionalStudy	blindingSchemaCode		Masking	Knowledge of intervention assignments (at least one of the following required: Intervention Model, Masking, Allocation. All may be required as part of Study Design under PL 110-85, Section 801) - Open: no masking is used. All involved know the identity of the intervention assignment. - Single Blind: one party, either the investigator or participant, is unaware of the intervention assignment; also called single-masked study. - Double Blind: two or more parties are unaware of the intervention assignment If Single Blind or Double Blind is selected, check the role(s) that are to be masked: Subject, Caregiver, Investigator or Outcomes Assessor.
9	InterventionalStudy	controlTypeCode		Study Type	A well-controlled study permits a comparison of subjects treated with the investigational drug with a suitable control population, so that the effect of the investigational drug can be determined and distinguished from other influences, such as spontaneous change, placebo effects, concomitant therapy, or observer expectations. [21 CFR 312.126]
10	InterventionalStudy	interventionDescription		Intervention(s)	Cover key details of the intervention. Must be sufficiently detailed to distinguish between arms of a study (e.g., comparison of different dosages of drug) and/or among similar interventions (e.g., comparison of multiple implantable cardiac defibrillators). For example, interventions involving drugs may include dosage form, dosage, frequency and duration.

ID	BRIDG Model Element			WHO.CTR Data Requirements	
	Class	Attribute	Comment	Data Item	Comment
11	Organization	name		Primary Sponsor (WHO CTR item 5)	Name of primary organization that oversees implementation of study and is responsible for data analysis. For applicable clinical trials, sponsor is defined in 21 CFR 50.3. Examples: National Institute of Allergy and Infectious Diseases, Bristol-Myers Squibb
12	Organization	name		Primary Sponsor (WHO CTR item 5)	The individual, organization, group or other legal entity which takes responsibility for initiating, managing and/or financing a study. The Primary Sponsor is responsible for ensuring that the ensuring that the trial is properly registered. The Primary Sponsor may or may not be the main funder.
13	Organization	name		Secondary Sponsor(s) (WHO CTR item 6)	Other organizations (if any) providing support, including funding, design, implementation, data analysis and reporting. The data provider is responsible for confirming all collaborators before listing them. Provide up to 10 full names of collaborating organizations.
14	Organization	name		Secondary Sponsor(s) (WHO CTR item 6)	Person is not defined in CT.gov
15	Organization	name		Source(s) of Monetary or Material Support (WHO CTR item 4)	Funding Organization
16	Organization	name		Source(s) of Monetary or Material Support (WHO CTR item 4)	Funding Person
17	Person	name		Contact for Public Queries (WHO CTR item 7)	Email address, telephone number, or postal address of the contact who will respond to general queries, including information about current recruitment status.
18	Person	name		Contact for Scientific Queries (WHO CTR item 8)	Person(s) responsible for the overall scientific leadership of the protocol, including study principal. First Name, Middle Initial, Last Name investigator.
19	Person	name		Contact for Scientific Queries (WHO CTR item 8)	Position or function of the official. Study Chair/Study Director/Study Principal Investigator

ID	BRIDG Model Element			WHO.CTR Data Requirements	
	Class	Attribute	Comment	Data Item	Comment
20	PlannedContingentOnRelationship	evaluableExpression	Proposed addition to BRIDG	inclusion/exclusion criteria	Maximum age of participants. Provide a number and a unit of time (years, months, weeks, days, hours or minutes). Select "N/A (No limit)" if no maximum age is indicated.
21	PlannedContingentOnRelationship	evaluableExpression	Proposed addition to BRIDG	inclusion/exclusion criteria	Minimum age of participants. Provide a number and select a unit of time (years, months, weeks, days, hours or minutes). Select "N/A (No limit)" if no minimum age is indicated.
22	PlannedContingentOnRelationship	evaluableExpression	Proposed addition to BRIDG	inclusion/exclusion criteria	Physical gender of individuals who may participate in the protocol. Select one. - Both: both female and male participants are being studied - Female: only female participants are being studied - Male: only male participants are being studied
23	Product	nameCode		Intervention	For drugs use generic name; for other types of interventions provide a brief descriptive name. For investigational new drugs that do not yet have a generic name, a chemical name, company code or serial number may be used on a temporary basis. As soon as the generic name has been established, update the associated protocol records accordingly. For non-drug intervention types, provide an intervention name with sufficient detail so that it can be distinguished from other similar interventions.

ID	BRIDG Model Element			WHO.CTR Data Requirements	
	Class	Attribute	Comment	Data Item	Comment
24	Study	~ derived based on specialization type		Study Type	Definition: Nature of the investigation. Select one. Interventional: studies in human beings in which individuals are assigned by an investigator based on a protocol to receive specific interventions. Subjects may receive diagnostic, therapeutic or other types of interventions. The assignment of the intervention may or may not be random. The individuals are then followed and biomedical and/or health outcomes are assessed. Observational: studies in human beings in which biomedical and/or health outcomes are assessed in pre-defined groups of individuals. Subjects in the study may receive diagnostic, therapeutic, or other interventions, but the investigator does not assign specific interventions to the subjects of the study. Expanded Access: records describing the procedure for obtaining an experimental drug or device for patients who are not adequately treated by existing therapy, who do not meet the eligibility criteria for enrollment, or who are otherwise unable to participate in a controlled clinical study. Expanded Access records are
25	Study	acronym		Acronym	Definition: Acronym or initials used to identify this study, if applicable. Enter only the acronym. If supplied, the acronym is automatically displayed in parentheses following the brief title. Example: Brief Title: Women's Health Initiative Acronym: WHI Displayed on ClinicalTrials.gov as: Women's Health Initiative (WHI)
26	Study	designConfigurationCode		Study Type	Clinical trial design developed to compare treatment groups in a clinical trial. NOTE: The configuration usually requires randomization to one or more treatment arms, each arm being allocated a different (or no) treatment. Examples include: Parallel Group Design, Crossover Design, Factorial Designs. [from ICH E9]

ID	BRIDG Model Element			WHO.CTR Data Requirements	
	Class	Attribute	Comment	Data Item	Comment
27	Study	designConfigurationCode		Study Type-Assignment	Plan for the precise procedure to be followed in a clinical trial, including planned and actual timing of events, choice of control group, method of allocating treatments, blinding methods; assigns a subject to pass through one or more epochs in the course of a trial. Specific design elements, e.g., crossover, parallel; dose-escalation [Modified from Pocock, Clinical Trials: A Practical Approach] See Trial Design Model. See also, arm, epoch, and visit.
28	Study	diseaseCode		Health Condition(s) or Problem(s) Studied (WHO CTR item 12)	Primary health condition(s) or problem(s) studied (e.g., depression, breast cancer, medication error). If the study is conducted in healthy human volunteers belonging to the target population of the intervention (e.g. preventive or screening interventions), enter the particular health condition(s) or problem(s) being prevented. If the study is conducted in healthy human volunteers not belonging to the target population (e.g., a preliminary safety study), an appropriate keyword will be defined for users to select.
29	Study	participatingCountryCode		Countries of Recruitment (WHO CTR item 11)	The countries from which participants will be, are intended to be, or have been recruited.
30	Study	phaseCode		Study Type.Phase (WHO CTR item 15)	Phase of investigation, as defined by the US FDA for trials involving investigational new drugs. (N/A, Phase 0, Phase 1, Phase 1/Phase2, Phase 2, Phase 2/Phase 3, Phase 3, Phase 4)
31	Study	populationDescription		Health Condition(s) or Problem(s) Studied (WHO CTR item 12)	Summary criteria for participant selection. The preferred format includes lists of inclusion and exclusion criteria as shown below. Example: Inclusion Criteria: - Clinical diagnosis of Alzheimer's Disease - Must be able to swallow tablets Exclusion Criteria: - Insulin dependent diabetes - Thyroid disease

ID	BRIDG Model Element			WHO.CTR Data Requirements	
	Class	Attribute	Comment	Data Item	Comment
32	Study	primaryPurposeCode		Intervention(s) Includes control interventions. For each intervention, describe other intervention details as applicable (dose, duration, mode of administration, etc) (WHO CTR item 13, more details there.)	Select one per intervention - Drug (including placebo) - Device (including sham) - Biological/Vaccine - Procedure/Surgery - Radiation - Behavioral (e.g., Psychotherapy, Lifestyle Counseling) - Genetic (including gene transfer, stem cell and recombinant DNA) - Dietary Supplement (e.g., vitamins, minerals) - Other
33	Study	primaryPurposeCode		Study Type - Purpose	Reason for the protocol - Treatment: protocol designed to evaluate one or more interventions for treating a disease, syndrome or condition - Prevention: protocol designed to assess one or more interventions aimed at preventing the development of a specific disease or health condition - Diagnostic: protocol designed to evaluate one or more interventions aimed at identifying a disease or health condition - Supportive Care: protocol designed to evaluate one or more interventions where the primary intent is to maximize comfort, minimize side effects or mitigate against a decline in the subject's health or function. In general, supportive care interventions are not intended to cure a disease. - Screening: protocol designed to assess or examine methods of identifying a condition (or risk factors for a condition) in people who are not yet known to have the condition (or risk factor). - Health Services Research: protocol designed to evaluate the delivery, processes, management, organization or financing of health
34	Study	targetAccuralNumberRange		Target Sample Size	Number of subjects in the trial. A "Type" menu is also included, with options Anticipated and Actual. For active studies, set Type to Anticipated and specify the expected enrollment, updating the number as needed over the course of the study. Upon study completion, change Type to Actual and update the enrollment if necessary.

ID	BRIDG Model Element			WHO.CTR Data Requirements	
	Class	Attribute	Comment	Data Item	Comment
35	StudyOutcomeMeasure	name		Primary Outcome(s), Key Secondary Outcomes Outcomes include • Outcome name • Timepoints • Measure	Measure
36	StudyOutcomeMeasure	name		Primary Outcome(s), Key Secondary Outcomes Outcomes include • Outcome name • Timepoints • Measure	Primary or Secondary?
37	StudyOutcomeMeasure	name		Primary Outcome(s), Key Secondary Outcomes Outcomes include • Outcome name • Timepoints • Measure	Time Frame
38	StudyOutcomeMeasure	typeCode		Primary Outcome(s), Key Secondary Outcomes Outcomes include • Outcome name • Timepoints • Measure	Type of primary outcome or endpoint that the protocol is designed to evaluate. Select one. - N/A: not applicable - Safety: show if the drug is safe under conditions of proposed use - Efficacy: measure of an intervention's influence on a disease or health condition - Safety/Efficacy - Bio-equivalence: scientific basis for comparing generic and brand name drugs - Bio-availability: rate and extent to which a drug is absorbed or otherwise available to the treatment site in the body - Pharmacokinetics: the action of a drug in the body over a period of time including the process of absorption, distribution and localization in tissue, biotransformation, and excretion of the compound - Pharmacodynamics: action of drugs in living systems - Pharmacokinetics/dynamics

ID	BRIDG Model Element			WHO.CTR Data Requirements	
	Class	Attribute	Comment	Data Item	Comment
39	StudyOverallStatus	statusCode		Recruitment Status (WHO CTR item 18)	Overall accrual activity for the protocol. Select one. Not yet recruiting: participants are not yet being recruited Recruiting: participants are currently being recruited Enrolling by invitation: participants are being (or will be) selected from a predetermined population Active, not recruiting: study is ongoing (i.e., patients are being treated or examined), but participants are not currently being recruited or enrolled Completed: the study has concluded normally; participants are no longer being examined or treated (i.e., last patient's last visit has occurred) Suspended: recruiting or enrolling participants has halted prematurely but potentially will resume Terminated: recruiting or enrolling participants has halted prematurely and will not resume; participants are no longer being examined or treated Withdrawn: study halted prematurely, prior to enrollment of first participant
40	StudyOverallStatus	statusDate		Date of First Enrollment (WHO CTR item 16)	Date that enrollment to the protocol begins.
41	StudyProtocolDocument	publicTitle		Public Title - Title intended for the lay public in easily understood language. (WHO CTR item 9)	Definition: Protocol title intended for the lay public. Example: Safety Study of Recombinant Vaccinia Virus Vaccine to Treat Prostate Cancer
42	StudyRecruitmentStatus	statusCode		Recruitment Status (WHO CTR item 18)	StudyRecruitmentStatus: Status of finding and enrolling appropriate subjects (those selected on the basis of the protocol's inclusion and exclusion criteria) into a clinical study. StudyOverallStatus: Describes the comprehensive state of the study.
43	StudyRegistry	acronym		Primary register (ASSIGNED ID NUMBER by the Registry) and Registry ID number (WHO CTR Item 1)	A unique identification given to a protocol by a registry.

ID	BRIDG Model Element			EMEA Data Requirement		
	Class	Attribute	Comment	Form Ref	Field Name	Comments
1	Arm	typeCode		**E.8.2.4**	Number Treatment Arms	
2	DefinedActivity	description		D.4.2.2.1	Type of differentiated cells	If D.5.2.2 = Y then this holds the description of the differentiated cell type (eg keratinocytes, fibroblasts, chondrocytes, etc).
3	DefinedActivity	description		D.4.2.3.1	Somatic Cell Therapy type other specification	If D.5.2.3 = Y then this holds a description for cell types other than stem and differentiated..
4	DefinedActivity	description		D.5.1	Gene therapy gene(s) of interest	Free text list of the genes of interest
5	DefinedActivity	description		D.5.5.4	GM cells Other specification	Enter here free text for the type of genetically modified cells (eg haematopoietic stem cells, etc)
6	DefinedActivity	nameCode		D.4.1.1	Somatic Cell Therapy origin autologous	If D.3.11.3 = Y is the origin of the cells autologous ?
7	DefinedActivity	nameCode		D.4.1.2	Somatic Cell Therapy origin allogeneic	If D.3.11.3 = Y is the origin of the cells allogeneic ?
8	DefinedActivity	nameCode		D.4.1.3	Somatic Cell Therapy origin xenogeneic	If D.3.11.3 = Y is the origin of the cells xenogeneic ?
9	DefinedActivity	nameCode		D.4.1.3.1	Somatic Cell Therapy xenogeneic species	If D.5.1.3 = Y then enter here the species of origin of xenogeneic cells
10	DefinedActivity	nameCode		D.4.2.1	Somatic Cell Therapy type stem	If D.3.11.3 = Y then is the type of cells stem ?
11	DefinedActivity	nameCode		D.4.2.2	Somatic Cell Therapy type differentiated	If D.3.11.3 = Y then is the type of cells differentiated ?
12	DefinedActivity	nameCode		D.4.2.3	Somatic Cell Therapy type other	A cell therapy type not identified in D.5.1.1 to D.5.2.2.1
13	DefinedActivity	nameCode		D.5.2	Gene therapy in-vivo	
14	DefinedActivity	nameCode		D.5.3	Gene therapy ex-vivo	
15	DefinedActivity	nameCode		D.5.4.1	Gene therapy nucleic acid	
16	DefinedActivity	nameCode		D.5.4.1.1	Gene therapy naked	
17	DefinedActivity	nameCode		D.5.4.1.2	Gene therapy complexed	
18	DefinedActivity	nameCode		D.5.4.2	Gene therapy viral vector	
19	DefinedActivity	nameCode		D.5.4.2.1	Gene therapy viral vector type	
20	DefinedActivity	nameCode		D.5.4.3	Gene Therapy other	Gene therapy other than Nucleic (Line 91=N)) or Viral (Line 94=N)
21	DefinedActivity	nameCode		D.5.4.3.1	Gene therapy other specification	If D.6.4.3 = Y then enter here free text for any other gene transfer product.
22	DefinedActivity	nameCode		D.5.5.1	GM cells origin autologous	If D.6.5 =Y is the origin of the genetically modified cells autologous ?
23	DefinedActivity	nameCode		D.5.5.2	GM cells origin allogeneic	If D.6.5 =Y is the origin of the genetically modified cells allogeneic ?
24	DefinedActivity	nameCode		D.5.5.3	GM cells origin xenogeneic	If D.6.5 =Y is the origin of the genetically modified cells xenogeneic ?

ID	BRIDG Model Element			EMEA Data Requirement		
	Class	Attribute	Comment	Form Ref	Field Name	Comments
25	DefinedActivity	nameCode		D.5.5.3.1	GM cells xenogeneic species	If D.6.5.3 = Y then enter here the species of origin of xenogeneic cells
26	DefinedActivity	nameCode		**D.6.1.1**	Tissue Engineered origin autologous	
27	DefinedActivity	nameCode		**D.6.1.2**	Tissue Engineered origin allogeneic	
28	DefinedActivity	nameCode		**D.6.1.3**	Tissue Engineered origin xenogeneic	
29	DefinedActivity	nameCode		**D.6.1.3.1**	Tissue Engineered xenogeneic species	
30	DefinedActivity	subcategoryCode		**D.3.4.1**	Specific paediatric formulation	
31	DefinedExclusionCriteria	nameCode	inherited from Defined Activity	E.4	Principal exclusion criteria	Included within a single text string (form guidance). (DB Guidance says “repeat as necessary”)
32	DefinedInclusionCriteria	nameCode	inherited from Defined Activity	E.3	Principal inclusion criteria	Included within a single text string (form guidance). (DB Guidance says “repeat as necessary”)
33	DefinedSupstanceAdministration	dailyDoseTotal		D.3.6.1	First dose in FIH Dose per Day or Total	
34	DefinedSupstanceAdministration	dailyDoseTotal		D.3.6.1	First dose in FIH Total Dose Unit	Use EV LK_CONCENTRATIONUNIT lookup table– drop down list (ICH “measureunit” + additional values). Longest unit name is 38 chrs: IU/mg international unit(s)/milligram
35	DefinedSupstanceAdministration	dailyDoseTotal		D.3.6.2	Maximum dose per Day or Total	
36	DefinedSupstanceAdministration	dose		D.3.6.1	First dose in FIH (First In Human) dose allowed	
37	DefinedSupstanceAdministration	dose		D.3.6.2	Maximum dose Total Dose Unit	Use EV LK_CONCENTRATIONUNIT lookup table– drop down list (ICH “measureunit” + additional values). Longest unit name is 38 chrs: IU/mg international unit(s)/milligram
38	DefinedSupstanceAdministration	repeatQuantity	inherited from Defined Activity	D.3.6.1	First dose in FIH Total Dose Number	
39	DefinedSupstanceAdministration	repeatQuantity	inherited from Defined Activity	D.3.6.2	Maximum dose Total Dose Number	
40	DefinedSupstanceAdministration	routOfAdministrationCode		D.3.6.1	First dose in FIH RoA	
41	DefinedSupstanceAdministration	routOfAdministrationCode		D.3.6.2	Maximum dose RoA	
42	DefinedSupstanceAdministration	routOfAdministrationCode		D.3.7	IMP Routes of Administration	Multi select
43	DefinedSupstanceAdministration	routOfAdministrationCode	inherited from Material	D.8.4	Placebo Route of administration	NOTE: This field repeats. There may be more than one Route of Administration for one placebo
44	Document	revisionNumberText		A.4.2	Sponsor protocol version	The sponsors version number for this protocol
45	Document	text		D.2.1.1.4.1	IMP modified specification	If Y to D.2.1.1.4 this is the text describing the modification
46	Document	typeCode		D.2.3.1	Full IMPD submitted	
47	Document	typeCode		D.2.3.2	Simplified IMPD submitted	
48	Document	typeCode		D.2.3.3	Only SmPC (Summary of Product Characteristics) submitted	
49	Document	versionDate	Proposed addition to BRIDG	A.4.3	Sponsor protocol version date	YYYYMMDD. The date of the this version of the sponsor's protocol

ID	BRIDG Model Element			EMEA Data Requirement		
	Class	Attribute	Comment	Form Ref	Field Name	Comments
50	Document	officialTitle		A.3	Full title of the trial	Free text. Field size changed from 500 to 2000 at 3.0.1
51	DocumentIdentifier	identifier		A.2	EudraCT number	yyyy-nnnnnn-cc. yyyy = year. nnnnnn is sequential within year. cc are check digits. [AA and A1 are the concatenated table key]
52	DocumentIdentifier	identifier		A.4.1	Sponsor protocol number	As ICH A.2.3.2 Sponsor Study Number.
53	DocumentIdentifier	identifier		A.5.1	ISRCTN number	Format ISRCTN99999999
54	DocumentIdentifier	identifier		**A.5.2**	US NCT number	Roughly, NCT numbers are 8 digits, ascending and correlated with registration date. More specifically, NCT00000100 - NCT00006520 are sequential with occasional random gaps (caused by deletions, errors, etc...) then we got a little smarter and started
55	DocumentIdentifier	identifier		**A.5.3**	WHO UTRN	
56	DocumentIdentifier	identifier		**A.5.4**	Other Identifier Name	Repeating as a pair with identifier
57	DocumentIdentifier	identifier		**A.5.4**	Other Identifier	Repeating as a pair with name
58	InteventionalStudy	populationDescription	Inherited from Study	F.3.1	Population healthy volunteers	
59	Material	description		**D.3.9.5**	AS molecular formula	
60	Material	description		**D.3.9.6**	AS description	
61	Material	formCode		D.3.4	IMP Pharmaceutical Form	
62	material	formCode	inherited from Material	D.8.3	Placebo Pharmaceutical form	
63	Material	identifier		D.1.1	IMP sequence number	Unique sequence number for the repeating products. Format: PRnn
64	material	material.description		**D.7.1**	Device description	
65	material	material.name		**D.7.2**	Device name	
66	Material	name		D.2.1.1.1	IMP Trade name	Product Tradename
67	Material	name		D.3.1	IMP Name	In the absence of a Tradename this is the name routinely used by the sponsor in the clinical trial documentation e.g. patient information leaflet, protocol, IB. If the sponsor does not have a specific product name, and only the active substance name or c

ID	BRIDG Model Element			EMEA Data Requirement		
	Class	Attribute	Comment	Form Ref	Field Name	Comments
68	Material	name		D.3.2	IMP Code	Code defined by the sponsor, potentially used in case of combination of drugs and devices but not routinely anticipated. This field is not required if the Tradename of an authorised product (in the EEA) has been provided. This field may be blank if no pr
69	Material	name		D.3.8	AS INN	The International Non-proprietary name for this active substance. ICH B.4.k.2.2 activesubstancename is 100AN. Pre 3.0.1 there were two fields for an INN and a Proposed INN. These two fields were combined into one at 3.0.1
70	Material	name		D.3.9.3	AS other descriptive name	Any other descriptive name for this active substance. Size increased to 500 chars in V8
71	Material	name		**D3.9.4**	EV (EudraVigilance) Substance Code	EV code of substance - field in use from 3.0.1
72	Organization	identifier		**B.5.8.2**	EV Sender ID	
73	Organization	name		A.1	Application NCA (National Competent Authority)	The NCA organisation that will be responsible for entering the data to the EudraCT database. This information will be used by the user access security system to ensure that NCAs can only enter and edit Applications for which they have responsibility.
74	Organization	name		B.1.1	Sponsor Organisation	Name of organisation managing this trial. EV Simple DB mahname has 100 – use the same as EV. See row 10dd
75	Organization	name		B.2.1	Legal Rep Organisation	There can be one and only one legal representative for a sponsor.
76	Organization	name		**B.4.1**	Source of Monetary or Material Support organisation name	Repeating with B.4.2
77	Organization	name		**B.5.1**	Further information contact Organisation	
78	Organization	name		**B.5.8.1**	EV Sender ID organisation	
79	Organization	name		C.1.4.1	CA Applicant Organisation	
80	Organization	name		C.2.5.1	IEC Applicant Organisation	
81	Organization	name		D.2.1.1.2	MA Holder	MA holder
82	Organization	name		G.1.5 / G.2.5	Investigator Institution Name	
83	Organization	name		G.1.5 / G.2.5	Investigator Institution Department	

ID	BRIDG Model Element			EMEA Data Requirement		
	Class	Attribute	Comment	Form Ref	Field Name	Comments
84	Organization	name		G.3.1	CTF Organisation	
85	Organization	name		G.3.1	CTF Department	
86	Organization	name		**G.4.1**	Network Organisation	
87	Organization	name		G.5.1.1	Subcontractor Organisation Name	
88	Organization	name		G.5.1.1	Subcontractor Department Name	
89	Organization	name		H.2.1	NCA Organisation	
90	Organization	name		H.2.1	IEC Organisation	
91	Organization	name	inherited from Material	D.9.2.2	Responsible Site Organisation	Name of the organisation within the Community responsible for the release of the IMP. Each IMP in turn needs to be referred to and identified for ID F.1.3 ICH A.3.1.2 Sender Identifier has 60 and EV Simple DB mahname has 100 – use the same as EV
92	Organization	postalAddress		A.1	Application MS (member state)	Calculated fields derived from Application NCA country. Not stored in the database.
93	Organization	postalAddress		**B.4.2**	Source of Monetary or Material Support country	EUTCT ID of the country. May be from any country in the world.
94	Organization	postalAddress	inherited from Material	D.9.2.4.1	Responsible Site Street Address	ICH A.3.1.4a (Sender Address)
95	Organization	postalAddress	inherited from Material	D.9.2.4.2	Responsible Site Town/City	As EV city field in DD_MAH.
96	Organization	postalAddress	inherited from Material	D.9.2.4.3	Responsible Site Post Code	ICH A.3.1.4d (Sender Address)
97	Organization	postalAddress	inherited from Material	D.9.2.4.4	Responsible Site Country	EUTCT ID of the country. Must be from the EEA/MS list only
98	Organization	postalAddress		H.2.2.1	NCA Street Address	ICH A.3.1.4a (Sender Address)
99	Organization	postalAddress		H.2.2.1	NCA Town/City	Town/city only. No detailed address. As EV city field in DD_MAH.
100	Organization	postalAddress		H.2.2.1	NCA Post Code	ICH A.3.1.4d (Sender Address)
101	Organization	postalAddress		H.2.2.1	NCA Country	EUTCT ID of the country. Must be from the EEA/MS list only
102	Organization	postalAddress		H.2.2.1	IEC Street Address	ICH A.3.1.4a (Sender Address)
103	Organization	postalAddress		H.2.2.1	IEC Town/City	Town/city only. No detailed address. As EV city field in DD_MAH.
104	Organization	postalAddress		H.2.2.1	IEC Post Code	ICH A.3.1.4d (Sender Address)
105	Organization	postalAddress		H.2.2.1	IEC Country	EUTCT ID of the country Must be from the EEA/MS list only
106	Organization	typeCode		B.3.1 and B.3.2	Sponsor Status	Reference table. Commercial or Non-commercial
107	OrganizationalContact	postalAddress		B.1.3.1	Sponsor Street Address	ICH A.3.1.4a (Sender Address)

ID	BRIDG Model Element			EMEA Data Requirement		
	Class	Attribute	Comment	Form Ref	Field Name	Comments
108	OrganizationalContact	postalAddress		B.1.3.2	Sponsor Town/City	Town/city only in database. As EV city field in DD_MAH.
109	OrganizationalContact	postalAddress		B.1.3.3	Sponsor Post Code	ICH A.3.1.4d (Sender Address)
110	OrganizationalContact	postalAddress		B.1.3.4	Sponsor Country	EUTCT ID of the country May be from any country in the world.
111	OrganizationalContact	postalAddress		B.2.3.1	Legal Rep Street Address	ICH A.3.1.4a (Sender Address)
112	OrganizationalContact	postalAddress		B.2.3.2	Legal Rep Town/City	Town/city only. No detailed address held in the database. As EV city field in DD_MAH.
113	OrganizationalContact	postalAddress		B.2.3.3	Legal Rep Post Code	ICH A.3.1.4d (Sender Address)
114	OrganizationalContact	postalAddress		B.2.3.4	Legal Rep Country	EUTCT ID of the country. Must be from the EEA list only
115	OrganizationalContact	postalAddress		C.1.4.3.1	CA Applicant Street Address	ICH A.3.1.4a (Sender Address)
116	OrganizationalContact	postalAddress		C.1.4.3.2	CA Applicant Town/City	Town/city only. No detailed address. As EV city field in DD_MAH.
117	OrganizationalContact	postalAddress		C.1.4.3.3	CA Applicant Post Code	ICH A.3.1.4d (Sender Address)
118	OrganizationalContact	postalAddress		C.1.4.3.4	CA Applicant Country	EUTCT ID of the country. Full worldwide list from Version 4.0.0
119	OrganizationalContact	postalAddress		C.2.5.3.1	IEC Applicant Street Address	ICH A.3.1.4a (Sender Address)
120	OrganizationalContact	postalAddress		C.2.5.3.2	IEC Applicant Town/City	Town/city only. No detailed address. As EV city field in DD_MAH.
121	OrganizationalContact	postalAddress		C.2.5.3.3	IEC Applicant Post Code	ICH A.3.1.4d (Sender Address)
122	OrganizationalContact	postalAddress		C.2.5.3.4	IEC Applicant Country	EUTCT ID of the country. Must be from the EEA list only
123	OrganizationalContact	telecomAddress		B.1.4	Sponsor Telephone	ICH ICSR DTD Version 2.1 separates Tel No. (10AN), extension (5AN) Telephone country code (3AN)(ICH A.3.1.4f,g,h respectively)
124	OrganizationalContact	telecomAddress		B.1.5	Sponsor Fax	ICH ICSR DTD Version 2.1 separates Fax No. (10AN), extension (5AN) and Fax country code (3AN).(ICH A.3.1.4i,j,k respectively).
125	OrganizationalContact	telecomAddress		B.1.6	Sponsor Email	ICH A.3.1.4l
126	OrganizationalContact	telecomAddress		B.2.4	Legal Rep Telephone	ICH ICSR DTD Version 2.1 separates Tel No. (10AN), extension (5AN) Telephone country code (3AN)(ICH A.3.1.4f,g,h respectively)

ID	BRIDG Model Element			EMEA Data Requirement		
	Class	Attribute	Comment	Form Ref	Field Name	Comments
127	OrganizationalContact	telecomAddress		B.2.5	Legal Rep Fax	ICH ICSR DTD Version 2.1 separates Fax No. (10AN), extension (5AN) and Fax country code (3AN).(ICH A.3.1.4i,j,k respectively).
128	OrganizationalContact	telecomAddress		B.2.5	Legal Rep Email	ICH A.3.1.4l
129	OrganizationalContact	telecomAddress		C.1.4.4	CA Applicant Telephone	ICH ICSR DTD Version 2.1 separates Tel No. (10AN), extension (5AN) Telephone country code (3AN)(ICH A.3.1.4f,g,h respectively)
130	OrganizationalContact	telecomAddress		C.1.4.5	CA Applicant Fax	ICH ICSR DTD Version 2.1 separates Fax No. (10AN), extension (5AN) and Fax country code (3AN).(ICH A.3.1.4i,j,k respectively).
131	OrganizationalContact	telecomAddress		C.1.4.6	CA Applicant Email	ICH A.3.1.4l
132	OrganizationalContact	telecomAddress		C.2.5.4	IEC Applicant Telephone	ICH ICSR DTD Version 2.1 separates Tel No. (10AN), extension (5AN) Telephone country code (3AN)(ICH A.3.1.4f,g,h respectively)
133	OrganizationalContact	telecomAddress		C.2.5.5	IEC Applicant Fax	ICH ICSR DTD Version 2.1 separates Fax No. (10AN), extension (5AN) and Fax country code (3AN).(ICH A.3.1.4i,j,k respectively).
134	OrganizationalContact	telecomAddress		C.2.5.6	IEC Applicant Email	ICH A.3.1.4l
135	OrganizationRelationship	typeCode		C.1.1, C.1.2 and C.1.3	CA (Competent Authority) Applicant Type	Identification of the CA applicant for this CT in this MS. Selection by drop down list : Sponsor or Legal representative of the Sponsor or Person or organisation authorised by the Sponsor
136	OrganizationRelationship	typeCode		C.2.1, C.2.2, C.2.3 and C.2.4	IEC (Independent Ethics Committee) Applicant Type	Identification of the IEC applicant for this CT in this MS. Selection by radio button or drop-down list.
137	Performer	typeCode	inherited from Material	D.9.2.1 and D.9.2.2	Responsible Site Role	Who is authorizing the release of the Final packaged & labeled product?
138	Person	name		B.1.2.1	Sponsor Contact Given name	Field lengths are as per ICH A.3.1.3c, A.3.1.3d and A.3.1.3e Sender Identifier
139	Person	name		B.1.2.2	Sponsor Contact Middle name	Field lengths are as per ICH A.3.1.3c, A.3.1.3d and A.3.1.3e Sender Identifier
140	Person	name		B.1.2.3	Sponsor Contact Family Name	Field lengths are as per ICH A.3.1.3c, A.3.1.3d and A.3.1.3e Sender Identifier
141	Person	name		B.2.2.1	Legal Rep Given Name	Field lengths are as per ICH A.3.1.3c, A.3.1.3d and A.3.1.3e Sender Identifier.

ID	BRIDG Model Element			EMEA Data Requirement		
	Class	Attribute	Comment	Form Ref	Field Name	Comments
142	Person	name		B.2.2.2	Legal Rep Middle name	Field lengths are as per ICH A.3.1.3c, A.3.1.3d and A.3.1.3e Sender Identifier.
143	Person	name		B.2.2.3	Legal Rep Family Name	Field lengths are as per ICH A.3.1.3c, A.3.1.3d and A.3.1.3e Sender Identifier.
144	Person	name		C.1.4.2.1	CA Applicant Given Name	
145	Person	name		C.1.4.2.2	CA Applicant Middle name	
146	Person	name		C.1.4.2.3	CA Applicant Family Name	
147	Person	name		C.2.5.2.1	IEC Applicant Given Name	
148	Person	name		C.2.5.2.2	IEC Applicant Middle name	
149	Person	name		C.2.5.2.3	IEC Applicant Family Name	
150	Person	name		G.1.1 / G.2.1	Investigator Given Name	Field lengths are as per ICH A.3.1.3c, A.3.1.3d and A.3.1.3e Sender Identifier.
151	Person	name		G.1.2 / G.2.2	Investigator Middle name	Field lengths are as per ICH A.3.1.3c, A.3.1.3d and A.3.1.3e Sender Identifier.
152	Person	name		G.1.3 / G.2.3	Investigator Family Name	Field lengths are as per ICH A.3.1.3c, A.3.1.3d and A.3.1.3e Sender Identifier.
153	Person	name		G.1.4 / G.2.4	Investigator qualifications	
154	Person	name		G.3.2.1	CTF Given Name	Field lengths are as per ICH A.3.1.3c, A.3.1.3d and A.3.1.3e Sender Identifier.
155	Person	name		G.3.2.2	CTF Middle name	Field lengths are as per ICH A.3.1.3c, A.3.1.3d and A.3.1.3e Sender Identifier.
156	Person	name		G.3.2.3	CTF Family Name	Field lengths are as per ICH A.3.1.3c, A.3.1.3d and A.3.1.3e Sender Identifier.
157	Person	name		**G.4.2.1**	Network Given Name	Field lengths are as per ICH A.3.1.3c, A.3.1.3d and A.3.1.3e Sender Identifier.
158	Person	name		**G.4.2.2**	Network Middle Name	Field lengths are as per ICH A.3.1.3c, A.3.1.3d and A.3.1.3e Sender Identifier.
159	Person	name		**G.4.2.3**	Network Family Name	Field lengths are as per ICH A.3.1.3c, A.3.1.3d and A.3.1.3e Sender Identifier.
160	Person	name		G.5.1.2.1	Subcontractor Given Name	Field lengths are as per ICH A.3.1.3c, A.3.1.3d and A.3.1.3e Sender Identifier.
161	Person	name		G.5.1.2.2	Subcontractor Middle name	Field lengths are as per ICH A.3.1.3c, A.3.1.3d and A.3.1.3e Sender Identifier.
162	Person	name		G.5.1.2.3	Subcontractor Family Name	Field lengths are as per ICH A.3.1.3c, A.3.1.3d and A.3.1.3e Sender Identifier.
163	Person	postalAddress		G.1.5.1 / G.2.5.1	Investigator Street Address	ICH A.3.1.4a (Sender Address)
164	Person	postalAddress		G.1.5.2 / G.2.5.2	Investigator Town/City	As EV city field in DD_MAH.
165	Person	postalAddress		G.1.5.3 / G.2.5.3	Investigator Post Code	ICH A.3.1.4d (Sender Address)

ID	BRIDG Model Element			EMEA Data Requirement		
	Class	Attribute	Comment	Form Ref	Field Name	Comments
166	Person	postalAddress		G.1.5.4 / G.2.5.4	Investigator Country	EUTCT ID of the country. Must be from the EEA/MS list only
167	Person	postalAddress		G.3.3.1	CTF Street Address	ICH A.3.1.4a (Sender Address)
168	Person	postalAddress		G.3.3.2	CTF Town/City	
169	Person	postalAddress		G.3.3.3	CTF Post Code	ICH A.3.1.4d (Sender Address)
170	Person	postalAddress		G.3.3.4	CTF Country	EUTCT ID of the country. This can be any country in the world.
171	Person	postalAddress		**G.4.3.1**	Network Street Address	ICH A.3.1.4a (Sender Address)
172	Person	postalAddress		**G.4.3.2**	Network Town/City	
173	Person	postalAddress		**G.4.3.3**	Network Post Code	ICH A.3.1.4d (Sender Address)
174	Person	postalAddress		**G.4.3.4**	Network Country	EUTCT ID of the country This can be any country in the world.
175	Person	postalAddress		G.5.1.3.1	Subcontractor Street Address	ICH A.3.1.4a (Sender Address)
176	Person	postalAddress		G.5.1.3.2	Subcontractor Town/City	
177	Person	postalAddress		G.5.1.3.3	Subcontractor Post Code	ICH A.3.1.4d (Sender Address)
178	Person	postalAddress		G.5.1.3.4	Subcontractor Country	EUTCT ID of the country This can be any country in the world..
179	Person	telcomAddress		G.1.6 / G.2.6	Investigator Telephone	
180	Person	telcomAddress		**G.1.7 / G.2.7**	Investigator Fax	
181	Person	telcomAddress		G.1.8 / G.2.8	Investigator Email	
182	Person	telcomAddress		G.3.4	CTF Telephone	ICH ICSR DTD Version 2.1 separates Tel No. (10AN), extension (5AN) Telephone country code (3AN)(ICH A.3.1.4f,g,h respectively)
183	Person	telecomAddress		**G.3.5**	CTF Fax	
184	Person	telecomAddress		**G.3.6**	CTF Email	
185	Person	telecomAddress		**G.4.4**	Network Telephone	
186	Person	telecomAddress		**G.4.5**	Network Fax	
187	Person	telecomAddress		**G.4.6**	Network Email	
188	Person	telecomAddress		G.5.1.4	Subcontractor Telephone	ICH ICSR DTD Version 2.1 separates Tel No. (10AN), extension (5AN) Telephone country code (3AN)(ICH A.3.1.4f,g,h respectively)
189	Person	telecomAddress		**G.5.1.5**	Subcontractor Fax	
190	Person	telecomAddress		**G.5.1.6**	Subcontractor Email	
191	PlannedActivity	description		G.3.7.11.1	CTF duties others description	
192	PlannedActivity	identifer	Inherited from Activity	G.3.7.1	CTF duties routine clinical pathology	
193	PlannedActivity	identifer	Inherited from Activity	G.3.7.10	CTF duties endpoint test	
194	PlannedActivity	identifer	Inherited from Activity	G.3.7.11	CTF duties others	
195	PlannedActivity	identifer	Inherited from Activity	G.3.7.2	CTF duties clinical chemistry	

ID	BRIDG Model Element			EMEA Data Requirement		
	Class	Attribute	Comment	Form Ref	Field Name	Comments
196	PlannedActivity	identifer	Inherited from Activity	G.3.7.3	CTF duties clinical haematology	
197	PlannedActivity	identifer	Inherited from Activity	G.3.7.4	CTF duties clinical microbiology	
198	PlannedActivity	identifer	Inherited from Activity	G.3.7.5	CTF duties histopathology	
199	PlannedActivity	identifer	Inherited from Activity	G.3.7.6	CTF duties serology endocrinology	
200	PlannedActivity	identifer	Inherited from Activity	G.3.7.7	CTF duties analytical chemistry	
201	PlannedActivity	identifer	Inherited from Activity	G.3.7.8	CTF duties ECG analysis	
202	PlannedActivity	identifer	Inherited from Activity	G.3.7.9	CTF duties medical image analysis	
203	PlannedActivity	identifer	Inherited from Activity	G.5.1.10	Subcontractor duties investigator recruitment	
204	PlannedActivity	identifer	Inherited from Activity	G.5.1.11	Subcontractor duties IVRS treatment	
205	PlannedActivity	identifer	Inherited from Activity	G.5.1.12	Subcontractor duties data management	
206	PlannedActivity	identifer	Inherited from Activity	G.5.1.13	Subcontractor duties edata capture	
207	PlannedActivity	identifer	Inherited from Activity	G.5.1.14	Subcontractor duties SUSAR reporting	
208	PlannedActivity	identifer	Inherited from Activity	G.5.1.15	Subcontractor duties quality assurance auditing	
209	PlannedActivity	identifer	Inherited from Activity	G.5.1.16	Subcontractor duties statistical analysis	Y/N New field at 3.0.1
210	PlannedActivity	identifer	Inherited from Activity	G.5.1.17	Subcontractor duties medical writing	
211	PlannedActivity	identifer	Inherited from Activity	G.5.1.18	Subcontractor duties others	
212	PlannedActivity	identifer	Inherited from Activity	G.5.1.18.1	Subcontractor duties others description	
213	PlannedActivity	identifer	Inherited from Activity	G.5.1.7	Subcontractor duties all sponsor tasks	(Y/N) There will be 10 options with selection buttons and the option of 'Other'
214	PlannedActivity	identifer	Inherited from Activity	G.5.1.8	Subcontractor duties monitoring	
215	PlannedActivity	identifer	Inherited from Activity	G.5.1.9	Subcontractor duties regulatory	
216	PlannedActivity	plannedDuration		D.3.5	Maximum duration of treatment	Pre-3.0.1 max duration and dose was in Section G and general to the whole trial. From 3.0.1 these fields are for each specific IMP
217	PlannedRandomizationBookAllocation	blindedDescription	Inherited from Planned Activity	E.8.1.3	Trial design Single blind	
218	PlannedRandomizationBookAllocation	blindedDescription	Inherited from Planned Activity	E.8.1.4	Trial design Double blind	
219	Product	classCode		D.3.11.10	GMO (Genetically Modified Organism) MP	Does the proposed clinical trial entail a medicinal product containing GMOs?
220	Product	classCode		**D.3.11.3**	Advanced Therapy MP	
221	Product	classCode		D.3.11.3.1	Somatic cell therapy MP	Does the proposed clinical trial entail a somatic cell therapy medicinal product ?
222	Product	classCode		D.3.11.3.2	Gene therapy MP	Does the proposed clinical trial entail a gene therapy medicinal product ?
223	Product	classCode		**D.3.11.3.3**	Tissue Engineered MP	
224	Product	classCode		**D.3.11.3.4**	Combination ATIMP	
225	Product	classCode		**D.3.11.3.5**	CAT (committee for Advanced therapies) Classification issued	
226	Product	classCode		**D.3.11.3.5.1**	CAT Classification	
227	Product	classCode		D.3.11.5	Radiopharmaceutical MP	Does the proposed clinical trial entail a radiopharmaceutical medicinal product ?

ID	BRIDG Model Element			EMEA Data Requirement		
	Class	Attribute	Comment	Form Ref	Field Name	Comments
228	Product	classCode		D.3.11.6	Immunological MP	Does the proposed clinical trial entail an immunological medicinal product (such as a vaccine, allergen, immune serum, etc) ?
229	Product	classCode		D.3.11.7	Plasma derived MP	Plasma derived medicinal product
230	Product	classCode		D.3.11.8	Extractive MP	Other extractive medicinal product
231	Product	classCode		**D.3.11.9**	Recombinant MP	
232	Product	classCode		D.3.3	IMP ATC Code	7-character alphanumeric at level 4. this should only be entered when the product is used in the clinical trial within the terms of the marketing authorisation.
233	Product	classCode		D.3.9.1	AS CAS (Chemical Abstract Service) number	
234	Product	description	inherited from Material	**D.6.2.2.1**	Tissue Engineered differentiated specification	
235	Product	description	inherited from Material	**D.6.2.3.1**	Tissue Engineered Other specification	
236	Product	description	inherited from Material	**D.7.4.5.1**	Device Other specification	
237	Product	description	inherited from Material	E.8.2.3.1	Other comparator specification	If line E.8.2.3 = 'Y' then specify here
238	Product	identifer	inherited from Material	D.9.2	Product sequence number	Product sequence number (row 31) for the products (IMPs) for which this is the responsible site.
239	Product	identifer	inherited from Material	D.9.2	Placebo sequence number	
240	Product	identifer	inherited from Material	**D.9.3**	IMP sequence number	Product sequence number for the products (IMPs) for which no responsible site is required
241	Product	identifer	inherited from Material	**D.9.4**	Placebo sequence number	Product sequence number for the products (IMPs) for which no responsible site is required
242	Product	identifier	inherited from Material	D.8.2	Placebo sequence number	Format: PLnn
243	Product	identifier	inherited from Material	D.8.5	Related IMP sequence number	Product sequence number (row 31) for the products (IMPs) for which this is a placebo.
244	Product	nameCode		D.2.1.1.1.1	EV Identifiable Product Code	
245	Product	nameCode		D.3.9.2	AS current sponsor code	The current code in use by the sponsor for this active substance.
246	Product	nameCode		D.5.5	GM cells	If D.3.11.4 = Y does this gene therapy involve genetically modified cells ?
247	Product	nameCode		**D.6.2.1**	Tissue Engineered type stem	
248	Product	nameCode		**D.6.2.2**	Tissue Engineered type differentiated	
249	Product	nameCode		**D.6.2.3**	Tissue Engineered Other	
250	Product	nameCode		D.8.5.2	Placebo identical to IMP	
251	Product	nameCode		D.8.5.2.1	Placebo major ingredients	
252	Product	nameCode		E.8.2.1	Comparator another MP	
253	Product	nameCode		E.8.2.2	Comparator a placebo	
254	Product	nameCode		E.8.2.3	Other comparator	

ID	BRIDG Model Element			EMEA Data Requirement		
	Class	Attribute	Comment	Form Ref	Field Name	Comments
255	Product	typeCode		D.3.11.11	Herbal MP	Does the proposed clinical trial entail a herbal medicinal product?
256	Product	typeCode		D.3.11.12	Homeopathic MP	Does the proposed clinical trial entail a homeopathic medicinal product?
257	Product	typeCode		D.3.11.13	Other MP	
258	Product	typeCode		D.3.11.13.1	Other MP Specification	
259	Product	typeCode		**D.3.11.4**	Combination product including device	
260	Product	typeCode		**D.7.3**	Device implantable	
261	Product	typeCode		**D.7.4.1**	Contains medical device	
262	Product	typeCode		**D.7.4.2**	Contains Bio-materials	
263	Product	typeCode		**D.7.4.3**	Contains Scaffolds	
264	Product	typeCode		**D.7.4.4**	Contains Matrices	
265	Product	typeCode		**D.7.4.5**	Device Other	
266	ProductPart	actionMode	Proposed addition to BRIDG	**D.3.12**	Mode of action	How the active substance works Free text (To respond to HMA's requests)
267	ProductPart	activeIngredientIndicator		D.3.11.1	Chemical origin AS	Does the product contain an active substance of chemical origin ?
268	ProductPart	activeIngredientIndicator		D.3.11.2	Biological origin AS	Does the product contain an active substance of biological or biotechnological origin ?
269	RegulatoryApplication	identifier		**A.8**	PIP Decision number	Format: P/xx/yyyy, where xx is a sequential number that may extend to 3 digits and yyyy is the year.
270	RegulatoryAssessment	assessmentCode		H.3.3.2 / H.3.3.3	IEC Opinion Given	
271	RegulatoryAssessment	assessmentDate		H.3.3.1	IEC Opinion date	yyyymmdd
272	RegulatoryAssessment	assessmentReasonCode	Proposed addition to BRIDG	D.9.2.5.1	Reason for no authorisation	
273	RegulatoryAssessment	assessmentReasonCode	Proposed addition to BRIDG	H.3.3.3.1	IEC Opinion not favourable reasons	
274	RegulatoryAssessment	identifier		D.2.1.1.3	MA number	MA number - equivalent to an NDA (new drug application).
275	RegulatoryAssessment	identifier		D.2.2.4.1	IMP identification other specification	To be completed only if the question above (D.2.2.4) is set to 'Y'
276	RegulatoryAssessment	identifier		D.2.5.1	Orphan drug number	If row 48 = Y then this is the orphan product designation number for this product and indication. Community register on orphan medicinal products format EU/n/nn/nnn. *NOTE: # is assigned by EMA*
277	RegulatoryAssessment	identifier		D.9.2.5	Manufacturer authorisation number	Change of meaning of this field from 3.0.1
278	RegulatoryAssessment	statusCode	Proposed addition to BRIDG	D.3.11.10.1	GMP MP Auth granted	If row 78 = Y is this authorised for contained use ?
279	RegulatoryAssessment	statusCode	Proposed addition to BRIDG	D.3.11.10.2	GMP MP Auth pending	If row 78 = Y is authorisation pending ?

ID	BRIDG Model Element			EMEA Data Requirement		
	Class	Attribute	Comment	Form Ref	Field Name	Comments
280	RegulatoryAssessment	statusCode	Proposed addition to BRIDG	H.3.1 / H.3.2 / H.3.3	IEC Opinion Status	Drop-down list.
281	RegulatoryAuthority	juridictionCode		**B.5.7.1**	SUSAR Reporting to NCAs	
282	RegulatoryAuthority	juridictionCode		**B.5.7.2**	SUSAR Reporting to EVCTM	
283	RegulatoryAuthority	juridictionCode		D.2.1.2	Country granting MA	EUTCT ID of the country that granted the MA. May be from any country in the world.
284	RegulatoryAuthority	juridictionCode		D.2.6.1.1	SA (Scientific Advice) from CHMP	
285	RegulatoryAuthority	juridictionCode		D.2.6.1.2	SA from NCA	
286	Service	typeCode		E.8.7	Trial has data monitoring committee	New field in 3.0.1
287	StratumGroup	groupNumber		E.8.1.5	Trial design Parallel group	
288	Study	diseaseCode		E.1.1	Medical condition	Free text entry
289	Study	diseaseCode		**E.1.1.1**	Medical condition in lay language	
290	Study	diseaseCode		E.1.2	MedDRA Version	MedDRA dictionary version.
291	Study	diseaseCode		E.1.2	MedDRA Level	MedDRA level One of HLGT;HLT;LLT;PT;SOC
292	Study	diseaseCode		E.1.2	MedDRA Code	MedDRA code
293	Study	diseaseCode		E.1.2	MedDRA Term	MedDRA term
294	Study	diseaseCode		E.1.2	MedDRA EUTCT ID	
295	Study	duration	Proposed addition to BRIDG	E.8.9.1	Estimated trial duration in MS years	
296	Study	duration	Proposed addition to BRIDG	E.8.9.1	Estimated trial duration in MS months	
297	Study	duration	Proposed addition to BRIDG	E.8.9.1	Estimated trial duration in MS days	New field at 3.0.1
298	Study	duration	Proposed addition to BRIDG	E.8.9.2	Estimated trial duration worldwide years	
299	Study	duration	Proposed addition to BRIDG	E.8.9.2	Estimated trial duration worldwide months	
300	Study	duration	Proposed addition to BRIDG	E.8.9.2	Estimated trial duration worldwide days	New field at 3.0.1
301	Study	phaseCode		E.7.1	Trial type Human pharmacology (Phase I)	
302	Study	populationDescription		F.1.1	Population under eighteen	If the trial population includes subjects < 18 years: A statement that this clinical trial carried out outside the EEA will be conducted in accordance with the ethical requirements of Directive 2001/20/EC and includes measures to minimise pain and distres
303	Study	populationDescription		F.1.1.1	Population in utero	
304	Study	populationDescription		**F.1.1.1.1**	Population number in utero	
305	Study	populationDescription		F.1.1.2	Population preterm newborn infants	
306	Study	populationDescription		**F.1.1.2.1**	Population number preterm newborn infants	
307	Study	populationDescription		F.1.1.3	Population newborns	
308	Study	populationDescription		**F.1.1.3.1**	Population number newborns	
309	Study	populationDescription		F.1.1.4	Population infants and toddlers	
310	Study	populationDescription		**F.1.1.4.1**	Population number infants and toddlers	
311	Study	populationDescription		F.1.1.5	Population children	
312	Study	populationDescription		**F.1.1.5.1**	Population number children	
313	Study	populationDescription		F.1.1.6	Population adolescents	
314	Study	populationDescription		**F.1.1.6.1**	Population number adolescents	
315	Study	populationDescription		F.1.2	Population adults	

ID	BRIDG Model Element			EMEA Data Requirement		
	Class	Attribute	Comment	Form Ref	Field Name	Comments
316	Study	populationDescription		**F.1.2.1**	Population number adults	
317	Study	populationDescription		F.1.3	Population elderly	
318	Study	populationDescription		**F.1.3.1**	Population number elderly	
319	Study	populationDescription		F.2.1	Population male	
320	Study	populationDescription		F.2.2	Population female	
321	Study	populationDescription		F.3.2	Population patients	
322	Study	populationDescription		F.3.3	Population specific vunerable populations	New field at 3.0.1
323	Study	populationDescription		F.3.3.1	Population women of child bearing potential no contraception	
324	Study	populationDescription		F.3.3.2	Population women of child bearing potential contraception	New field at 3.0.1
325	Study	populationDescription		F.3.3.3	Population pregnant women	
326	Study	populationDescription		F.3.3.4	Population nursing women	
327	Study	populationDescription		F.3.3.5	Population emergency situation	
328	Study	populationDescription		F.3.3.6	Population subjects incapable of giving consent	
329	Study	populationDescription		F.3.3.6.1	Population subjects incapable of giving consent details	If line F.3.3.6 = 'Y' then specify here
330	Study	populationDescription		F.3.3.7	Population other subjects	
331	Study	populationDescription		F.3.3.7.1	Population other subjects details	If line F.3.3.7 = 'Y' then specify here.
332	Study	populationDescription		**New**	Population number under eighteen	
333	Study	targetAccrualNumberRange		F.4.2.2	Population planned numbers in whole trial	
334	Study	typeCode	Proposed addition to BRIDG	E.7.1.1	Trial type First administration to humans	
335	Study	typeCode	Proposed addition to BRIDG	E.7.1.2	Trial type Bioequivalence Study	
336	Study	typeCode	Proposed addition to BRIDG	E.7.1.3	Trial type Other	
337	Study	typeCode	Proposed addition to BRIDG	E.7.1.3.1	Trial type Other specification	If line E.7.1.3 = 'Y' then specify here
338	Study	typeCode	Proposed addition to BRIDG	E.7.2	Trial type Therapeutic Exploratory (Phase II)	
339	Study	typeCode	Proposed addition to BRIDG	E.7.3	Trial type Therapeutic Confirmatory (Phase III)	
340	Study	typeCode	Proposed addition to BRIDG	E.7.4	Trial type Therapeutic Use (Phase IV)	
341	Study	acronym		**A.3.2**	Abbreviated title of trial	As ICH A.2.3.1 Study Name.
342	StudyAgent	firstInHumanIndicator	Proposed addition to BRIDG	**D.3.13**	First in Human	(To respond to HMA's requests)
343	StudyAgent	firstInHumanRiskFactor	Proposed addition to BRIDG	**D.3.13.1**	First in Human Risk Factors	(To respond to HMA's requests)
344	StudyAgent	functionCode		D.1.2 and D.1.3	IMP Category	Field to describe the role of the product in the trial.
345	StudyColleague	postalAddress		**B.5.3.1**	Contact point for further information on the trial Street Address	ICH A.3.1.4a (Sender Address)
346	StudyColleague	postalAddress		**B.5.3.2**	Further information contact Town/City	Town/city only. No detailed address held in the database. As EV city field in DD_MAH.
347	StudyColleague	postalAddress		**B.5.3.3**	Further information contact Post Code	ICH A.3.1.4d (Sender Address)
348	StudyColleague	postalAddress		**B.5.3.4**	Further information contact Country	EUTCT ID of the country. Must be from the EEA list only
349	StudyColleague	roleCode		**B.5.2**	Further information contact name	Field lengths are as per ICH A.3.1.3c, A.3.1.3d and A.3.1.3e Sender Identifier.

ID	BRIDG Model Element			EMEA Data Requirement		
	Class	Attribute	Comment	Form Ref	Field Name	Comments
350	StudyColleague	telecomAddress		**B.5.4**	Further information contact Telephone	ICH ICSR DTD Version 2.1 separates Tel No. (10AN), extension (5AN) Telephone country code (3AN)(ICH A.3.1.4f,g,h respectively)
351	StudyColleague	telecomAddress		**B.5.5**	Further information contact Fax	ICH ICSR DTD Version 2.1 separates Fax No. (10AN), extension (5AN) and Fax country code (3AN).(ICH A.3.1.4i,j,k respectively).
352	StudyColleague	telecomAddress		**B.5.6**	Further information contact E-mail	ICH A.3.1.4l
353	StudyObjective	description		E.2.1	Trial main objective	
354	StudyObjective	description		E.2.2	Trial secondary objective	Included within a single text string (form guidance). (DB Guidance says “repeat as necessary”)
355	studyOutcomeMeasure	name		E.5.1	Primary end points	Included within a single text string (form guidance). Repeating
356	studyOutcomeMeasure	name		**E.5.2**	Secondary end point	Included within a single text string (form guidance). Repeating
357	studyOutcomeMeasure	timeFrameText		**E.5.1.1**	Primary end point timepoint	Linked to each endpoint
358	studyOutcomeMeasure	timeFrameText		**E.5.2.1**	Secondary end point timepoint	Linked to each endpoint
359	studyOutcomeMeasure	typeCode		E.6	Trial scope	
360	studyOutcomeMeasure	typeCode		E.6.1	Trial scope Diagnosis	
361	studyOutcomeMeasure	typeCode		E.6.10	Trial scope Pharmacogenetic	New field at 3.0.1
362	studyOutcomeMeasure	typeCode		E.6.11	Trial scope Pharmacogenomic	
363	studyOutcomeMeasure	typeCode		E.6.12	Trial scope Pharmacoeconomic	
364	studyOutcomeMeasure	typeCode		E.6.13	Trial scope Other	
365	studyOutcomeMeasure	typeCode		E.6.13.1	Trial scope Other specification	If line E.6.13 =”Y” then specify here.
366	studyOutcomeMeasure	typeCode		E.6.2	Trial scope Prophylaxis	
367	studyOutcomeMeasure	typeCode		E.6.3	Trial scope Therapy	
368	studyOutcomeMeasure	typeCode		E.6.4	Trial scope Safety	
369	studyOutcomeMeasure	typeCode		E.6.5	Trial scope Efficacy	
370	studyOutcomeMeasure	typeCode		E.6.6	Trial scope Pharmacokinetic	
371	studyOutcomeMeasure	typeCode		E.6.7	Trial scope Pharmacodynamic	
372	studyOutcomeMeasure	typeCode		E.6.8	Trial scope Bioequivalence	
373	studyOutcomeMeasure	typeCode		E.6.9	Trial scope Dose response	
374	StudyProtocolDocument	publicTitle		**A.3.1**	Title of the trial for lay people	
375	StudySite	targetAccrualNumberRange		F.4.1	Population planned numbers in MS	
376	StudySite	targetAccrualNumberRange		F.4.2.1	Population planned numbers in EEA	
377	Submission	receiptDate		H.2.3	NCA Submission date	
378	Submission	receiptDate		H.2.3	IEC Submission date	yyyymmdd
379	Submission	typeCode		A.6	Is resubmission	Resubmission question