DATASET UPLOAD REFERENCE: REQUESTED DESCRIPTIVE INFORMATION

Project Data Sphere®

Below is a list of requested descriptive information concerning each dataset that you provide within the "Share Data" section of the platform. Although not all fields are required, data providers are encouraged to provide as much information as possible to help users understand the provided data.

FIELD	REQUIRED/ OPTIONAL	CHARACTER LIMIT	BRIEF DESCRIPTION
Sponsor	**Required**	255	Organization who sponsored the study as described in the study protocol. If appropriate, provide clarifications in brackets, e.g. company name has changed since the study protocol was published.
Study Start Year	**Required**	Date	Year the study started
Outcome Measures	**Required**	1000	Concise summary of the outcomes documented in the study protocol or study report summary documents.
Clinical Trial Title	**Required**	600	The official study name documented in the study protocol
Trial Summary and Conditions	**Required**	5000	Please provide all relevant information about the trial design and study rationale in a concise summary. Please refer to the "Brief Summary" field in www.clinicaltrials.gov.
Data Summary	**Required**	1000	Please provide a concise summary of the data provided. For example, control arm data files include raw data on safety, efficacy, demographics, etc.
Study Objectives	**Required**	2000	Study objectives that are documented in the clinical study protocol. Please refer to the primary and secondary objectives as outlined in the protocol or study report.
Total Study Enrolled Patients	**Required**	10	Provide the total number of patients/participants enrolled per the clinical study report. Also refer to the "Enrollment" field in www.clinicaltrials.gov.
Comparator (Control) Arm Enrolled Patients	**Required**	10	Provide the total number of patients/participants only in the Comparator (Control) Arm dataset that you are uploading.
Randomization	**Required**	LOV	List of Values: Yes, No
Blinding Method	**Required**	LOV	List of Values: Double-Blinded Open Label Study, Single Blinded, Other
Intervention Type	**Required**	LOV	List of Values: Best Supportive Care, Biologics, Chemotherapy, Hormones, Placebo, Radiation, Surgery, Vaccines, Other
Dataset Type	**Required**	LOV	List of Values: ADS, SDTM, Other
Cancer Stage	**Required**	LOV	List of Values: Stage 0, Stage I, Stage II, Stage III, Stage IV, Other
Study Phase	**Required**	LOV	List of Values: Clinical Study Phase IIB, Clinical Study Phase III

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Tumor Type	Optional	LOV	List of Values: All, Bladder, Bone Sarcoma, Brain (Primary),Brain Metastasis, Breast, Colorectal, Endocrine Malignancies, Esophageal, Gallbladder and Biliary Tract, Gastric, GIST, Head & Neck, Kidney, Leukemia, Liver, Lung (Non-Small Cell), Lung (Small Cell), Lymphoma (Hodgkins), Lymphoma (Non-Hodgkins), Melanoma, Mesothelioma, Multiple Myeloma, Myelodysplastic Syndrome (MDS), Neuroendocrine Tumors, Ovarian, Pancreatic, Prostate, Skin (Non-Melanoma), Small Bowel, Soft Tissue Sarcoma, Testicular, Uterine Cervix, Other
Region	**Required**	LOV	List of Values: Africa, Asia-Pacific, Europe, North America, South/ Central America
Age Range	**Required**	LOV	List of Values: None, Adult (18-65), Elderly (66+)
ClinicalTrial.gov ID	Optional	25	If study is listed on www.clinicaltrials.gov provide the ID code
ClinicalTrial.gov URL	Optional	255	If study is listed on www.clinicaltrials.gov provide the web link

FIELD	REQUIRED/ OPTIONAL	CHARACTER LIMIT	BRIEF DESCRIPTION
Unique Patient Identifier Field	**Required**	255	Provide the name of the field that contains the unique patient ID for this de-identified data.
Date/Time Variables	**Optional**	600	To assist *Project Data Sphere* users, consider describing how dates/ times of events have been represented in the data being uploaded (e.g. relative dates, offset dates, or another method).
Efficacy Endpoints	**Required**	600	Briefly explain how efficacy endpoints are described in the data.
Domains or variables that capture efficacy endpoints	**Required**	600	Identify which DOMAINs and variables capture this information (e.g. death flag).
Was PRO data captured as part of this study?	**Required**	LOV	Select "yes" if Patient Reported Outcome ("PRO") data was captured as part of this study.
If yes, are you providing them as part of this upload?	**Required**	LOV	Select "yes" if PRO data was captured and will be uploaded as part of this submission.
If yes, please indicate which file(s) contain the PRO data	**Required**	600	Identify the file(s) containing PRO data to assist *Project Data Sphere* users.
Does this data set use custom formats?	**Required**	LOV	If custom formats are used, consider providing the format catalog using the proc format control option to assist *Project Data Sphere* users. Contact info@ProjectDataSphere.org for more information.
If yes, is the data set decoded?	**Required**	LOV	Select "yes" if the custom formats have been decoded.
Patient Breakdown	**Optional**	600	Optionally, provide a breakdown of patient demographics and flow for participants in this study.

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Required Data Files
In addition to the information above, data providers are required to provide the files listed below to complete their upload. Additionally, data providers are encouraged to provide other files that will assist the usage of the data (e.g. programmer notes) by other authorized users. **Please give each file a descriptive name to facilitate use by authorized users of the platform (e.g. include "Protocol" in the name of the Protocol file).**

REQUIRED FILE	FILE TYPE	NAMING STANDARDS	EXAMPLE
Study Protocol	One file in the following formats: pdf, doc, docx, txt, rtf	Include "sponsor name", "study protocol" and a "descriptor for the study" in the file name.	Sponsor Study Protocol Study Name.pdf
Case Report Form	One file in the following formats: pdf, doc, docx, txt, rtf	Include "sponsor name", "CRF", and a "descriptor for this study" in the file name.	Sponsor CRF Study Name.pdf
Data Descriptors/ Data Dictionary	May be multiple files in the following formats: pdf, doc, docx, txt, rtf, xls, wps, xml, xpt, cpt, lst, mdb, csv, ppt, rar, dtd, numbers, pages, zip	Include "sponsor name" and "data descriptors" and a "descriptor for this study". If more than one file, please ensure the "descriptor for this study" explains the content of the file.	Sponsor data descriptors AE data.xls
Datasets	May be multiple files in the following formats: sas7bdat, zip, pdf, doc, docx, txt, rtf, xls, wps, xml, xpt, cpt, lst, mdb, csv, ppt, rar, dtd, numbers, pages	Include "sponsor name" and "data" and a "descriptor for this study".	Sponsor data toxicology.db7. bat