User Stories

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Changes

- 25th January 2022 – Initial draft
- 31st January 2022 – Updates after informal review
- 14th February 2022 – Updates after initial Transcelerate (TCB) review. Includes better alignment with TCB terminology. Also, the Essential User Stories and those raised as JIRA tickets have been incorporated such they can viewed in context.
- 21st March 2022 – Updates after further review.

Purpose

This note presents a set of user stories for the Digital Data Flow Project based on the essential user stories produced by the project to date. The presented user stories try and respond to comments raised on the essential user stories such as the following JIRA ticket.

> *However the users of the USDM are the upstream and downstream systems and not directly the users of those systems. So search and add/remove functions like described in user story L1 to L5 are not directly applicable to the USDM and RA. However, the data structure must make it possible for the upstream system to provide this functionality. So a logical data structure and API requests are in scope. Can the user stories be adjusted to reflect this?*

System Functions

Overview

To assist with developing these user stories for upstream and downstream systems it is advisable to think in terms of functions a system may fulfil rather than any current system implementation. Systems may implement one or more system functions. Thinking in these terms prevents our thinking being constrained by current system functionality.

The envisaged system functions are described below, and example implementations are included at the end to provide additional explanation.

Protocol Writer

A system function that allows for the creation and maintenance of a protocol document.

Study Designer

A system function that allows for the creation of the study design element of a protocol.

Study Detail Creation

A system function that allows for the creation of a design for a study to the level of detail needed by collection systems to perform their task.

Study Definitions Repository

A system function that allows for the maintenance of study designs for use across the enterprise. The system function is solely concerned with the maintenance of complete study designs for use in the execution of studies.

Collection

A system function that allows for the task of collecting the data for a study.

Metadata Definitions Repository

A system function that allows for the maintaining one or more definitions for use by other systems (metadata). The definitions maintained are general ones that are for use by a range of systems, for example industry and sponsor's terminology.

Other

A system function, yet to be envisaged, for a more peripheral system in the current enterprise.

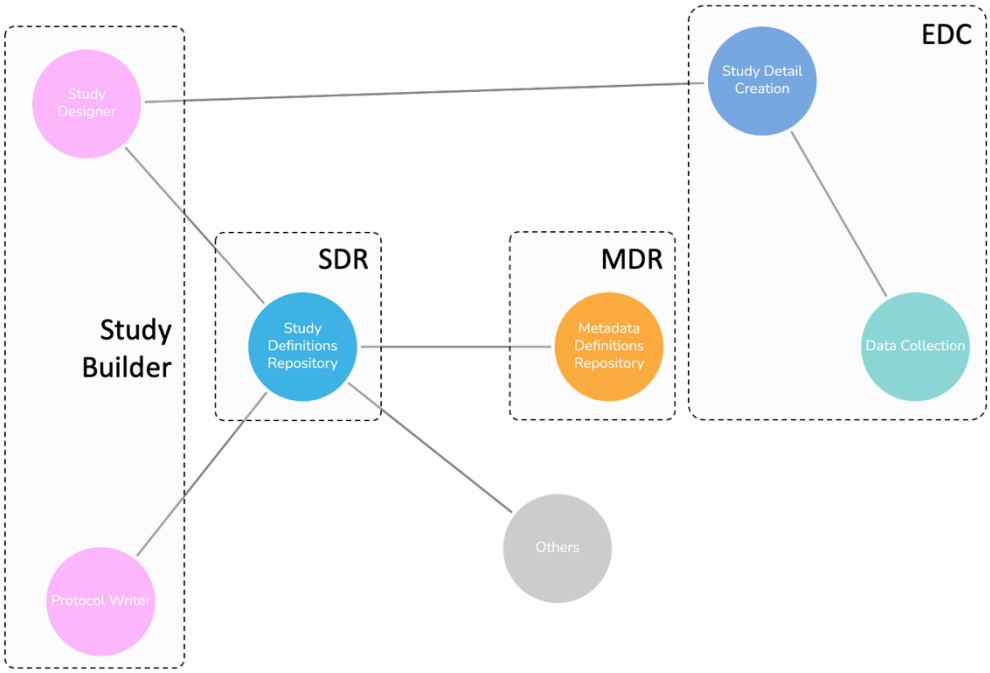
Actual System Examples

The above are system functions, that can be implemented singularly or together within a single system. For example:

- Metadata Definitions Repository:
    - Metadata Repository: The Metadata Definitions Repository system function would be implemented by what we would consider a Metadata Repository (MDR) today that would maintain a set of definitions (CDISC CT, SDTM etc) for use by a wide range of systems.
- Study Detail Creation:
    - EDC: An EDC system would typically implement the Study Detail Creation system function where the precise definition of the study would be created such that data can be captured. The process may rely on another system (see Definitions Repository and MDR) for source information or maintain an internal library of forms. A design may be received electronically or be entered by hand from a protocol document.

      The EDC system would also implement the Collection system function to capture the actual data.

    - ePRO: Another example of a system that would implement the Study Detail Creation and the Collection system function.
- Study Builder:
    - In the future we might see systems implement the Study Designer and Protocol Writer functions implemented within a single system.


EDC
Study Detail Creation
Study Designer
SDR
MDR
Study Builder
Study Definitions Repository
Metadata Definitions Repository
Data Collection
Others
Protocol Writer

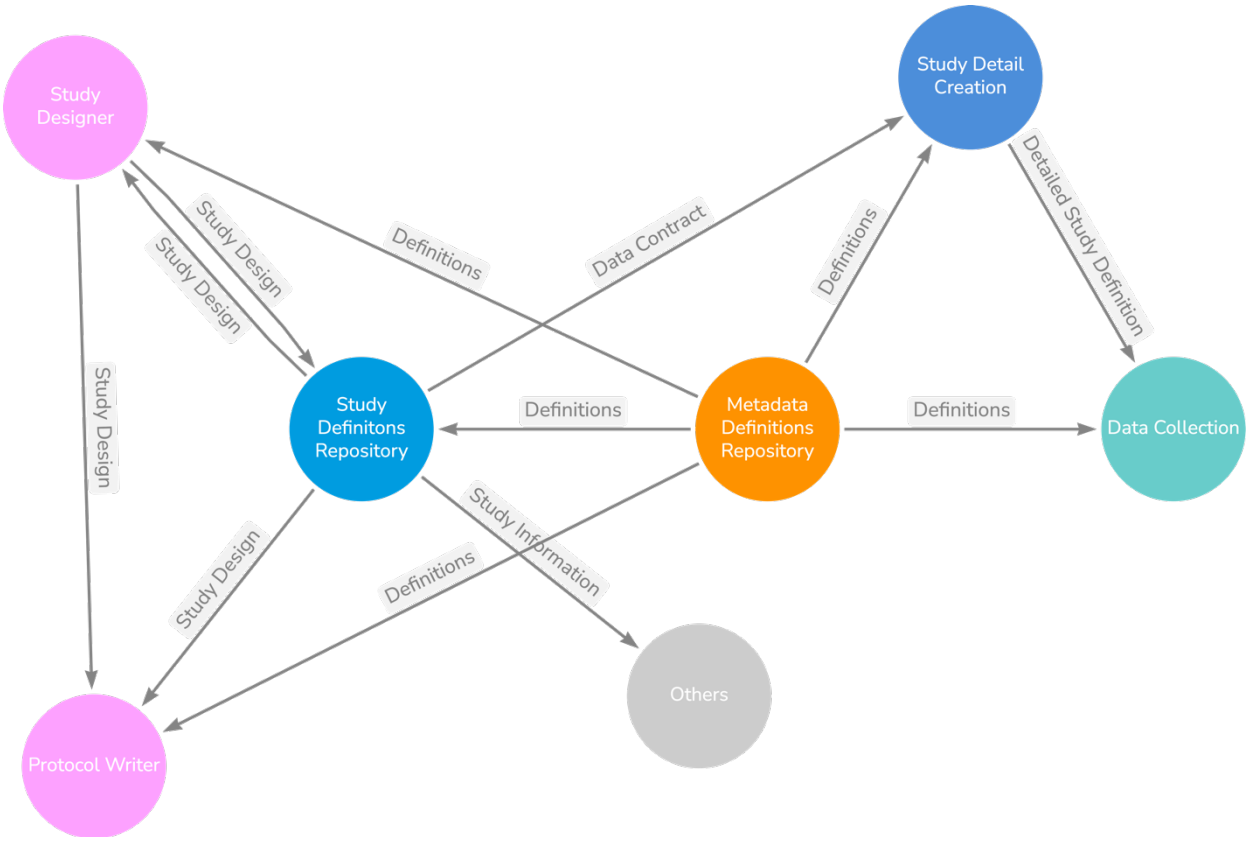
Information Flow

Overview

With the roles described above we can then think about the high-level information flows between the various system functions:

Flows

1. Study Design – A complete machine-readable design that we typically see within a protocol document today.
2. Data Contract – An extract of the study design focused on the data collection aspects of the study. This is the definition of the data needed to meet the needs of the study objectives but will not include evey detail on how that data is collected. Note that the collection system function covers a wide range of systemsm EDC, ePRO, Laboratory etc.
3. Study Information – A subset of study design as required by a system function. This could vary greatly and depends on the consuming system. It might be basic Study information like title and identifier. It might be the entire Schedule of Assements (SoA)
4. Definitions – Any common definitions required by a system function. This might be a CDISC code list, an SDTM domain, a single form definition.
5. Detailed Study Definition – The set of information that allows for the collection of data from a study. For an EDC system this would include the full set of form definitions for the study detailing each question and answer along with edit checks and all the other definitions the collection process requires.



User Stories

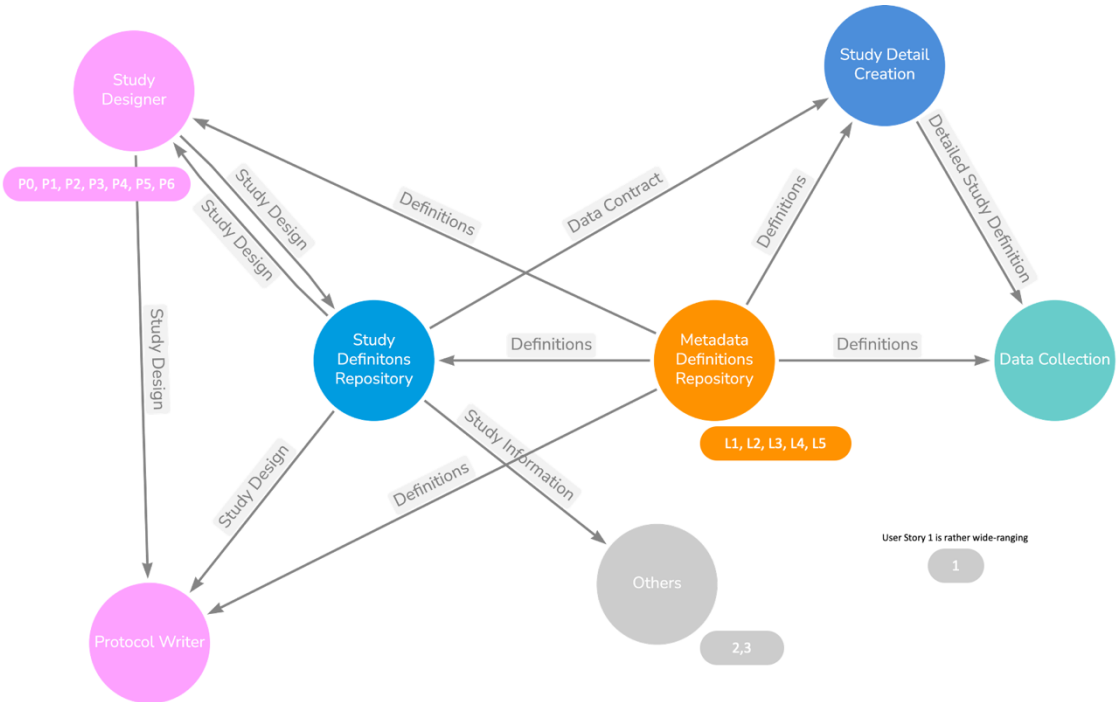
Overview

Each of the user stories is written from the perspective of a user of a system that implements a specific system function described above. It should be remembered that an actual system can implement one or more system functions.

Note that in the user stories detailed below, the user roles are explicitly noted or a generic role of <user role> is used. This generic user role could be replaced by a specific role.

Existing User Stories

The existing Essential User Stories map to the following roles as depicted in the following figure:



The essential user stories were written from the perspective of other systems and their respective users. They have been used to develop the user stories in the next section that are written with a focus on the needs of the Study Definitions Repository.

Study Designer Function

- As an Author I wish to be able to enter an XXX Study Design such that I have a machine-readable study design that can be shared with other systems to save data re-entry and consequent errors.

  Note: The requirement for XXX Study Design can be replaced with Simple, Cross-over etc to amplify the range of designs, in increasing complexity, that should be handled. This would result in N user stories for N study Designs. This user story drives the need for the USDM model to handle the range of study designs.

By stating the designs to be handled, it also allows for an incremental development and capability to be built in the software rather than trying to build using an "all in one" big-bang approach.

- As an Author I wish to be able to store a Study Design in my organisation's Study Definitions Repository such that it is available to other users of any system within my organisation.

  Note: This sharing user story, plus the one below, drives the need for an API. Also, the storing and availability of a design in the Study Definitions Repository drives the need for a common model.

- As an Author I wish to be able to retrieve a Study Design from my organisation's Study Definitions Repository such that a new version can be developed.
- As an Author I wish to be able to retrieve a Study Design from my organisation's Study Definitions Repository such that if can form the basis of a new study design (a cut and paste operation).

Study Definitions Repository Function

- As a <user role> I wish to be able to view the study designs with the Study Design Repository to see what designs are available.
- As a <user> I wish to compare versions of a study design to see the changes made.

Study Detail Creation Function

- As a <user role > I wish to be able to import a study data contract such that a Detailed Study Definition can be created allowing for the configuration of a data capture system.

Protocol Writer Function

- As a <user role > I wish to be able to import study definitions/study elements into a protocol document template such that the document is complete.

Metadata Definitions Function

- As a Librarian I wish to be able to create the necessary definitions for use in the creation of a Study Design such that study designs are standardised and reusable.

  Note: Study Designer Functions may require industry standard components such as controlled terminology, end points etc to build a study design. These may well be managed with a Metadata Repository.

Collection Function

- As a <user role > I wish to be able to import a detailed study definition such that the configuration of the capture system can be automated as much as is technically possible.

Other Function

- As a <user role > I wish to be able to have access to the details of a study in my organisation's study Definitions Repository such that relevant information can be employed within my workflow

  Note: This is a very high-level user story. The other system could be a Clinical Trial Management System needing details regarding a particular study design. The other system might be a regulatory system making submissions to trial registries and needing details such regarding a study. This user story could be decomposed, and several precise user stories developed.

Existing User Stories

General

This section lists the existing user stories for reference. Just the user stories are listed here and not the acceptance criteria.

Overall Series

Ref	Text	Outcome
1	As a User I want to have the study builder enable navigation to be able to access each module separately and complete the necessary design modules below for a selected study: 1) Reference Library Management (reference to User Stories, L1-L5) 2) Study Level Content (reference to User Story P0) 3) Protocol Level Content (reference to User Story P1-P6) 4) Schedule of Activities (reference to User Story P5) So that a user can navigate throughout the Study Builder.	Study Designer function user story. No further action.
2	As a reporting technology I want to be able to connect and access any data from the study builder so that I can build any requested report, dashboard and/or analytics	See "Other Function" above
3	As a User I want to 1) Select the protocol content for inclusion in export 2) Export my protocol content in various formats (e.g. CSV, RDF, XML, JSON for example) So that the data is available for ingestion into other systems.	See "Other Function" above. Also, the focus of the DDF project is currently on APIs rather than exports

L Series

Ref	Text	Outcome
L1	As a “Librarian” I want to be able to add, modify, inactivate, reactivate a reference library study design element and the associated attributes.	A Metadata Definitions user story
L2	As a “Librarian” I want to select which study design element I want to manage. I then want to add/modify/inactivate/reactivate/delete actual values for that element. So that those values are available for relationship management and for selection throughout the study builder. For example, I want to select the study design element of Indication and manage the list of available indication values.	A Metadata Definitions user story
L3	As a “Librarian” I want to select which study design element relationship I want to manage so that I can manage the standard relationships between the enterprise level design elements and capture which are required. For example, I want to select the study design element of Indication and see a list of the other elements. (below) Select one or multiple from those elements that related to the indication and indicate which of those relationships is mandatory.	A Metadata Definitions user story
L4	As a librarian I want to select which study design element I want to manage. I then want to select which relationship design element to manage. So that I can relate the associate values. For example, I want to select the study design element of Indication and see a list of available indications to manage. I then want to select the study design element relationship to manage. I should then see all available values for the design element to manage those relationships. I should be able to hit a save action to save my change. I should be able to hit a cancel action to cancel my changes.	A Metadata Definitions user story

P Series

Ref	Text	Resolution
P0	As an author I want to 1) Define a new study 2) Have the study builder surface a list of authorized study IDs (from mock data) 3) Select a study number from surfaced list OR add new a) If select predefined study ID, have the study builder automatically populate related values based on selected study ID; b) If add new, have the study builder surface list of available values (e.g., Therapeutic Area, Indication, Study Phase, and Study Type) to select from 4) Have the study builder store the study ID and its Study Level values So that I can initiate a new study build and trigger the availability of the remaining relevant Protocol Level Content.	A Study Designer user story.
P1	As a Author I want to 1) Select a study to create and edit protocol content (Reference User Story P0) 2) Describe my study by populating protocol level content values 3) Be able to select values from a controlled value list (As defined in User Story L1-L5) 4) Be able to enter free-text values for specified fields So that I can define the protocol level content	A Study Designer user story
P2	As an author I want to or remove objectives for the protocol 1) Select the study (P0) 2) Have the study builder surface related study objectives based on a defined study values (P0, P1) and related library values (L1-L5) 3) Choose the applicable objectives and have the study builder store them as part of the study design 4) If there are no previously linked objectives for the indication that match my need, then the study builder will display all objectives and let author pick one(s) relevant for my indication So that my study protocol is based on pre-defined library values	A Study Designer user story

P3	As an author I want to select or remove end points for the protocol 1) Select the study (P0) 2) Have the study builder surface related study endpoints based on a defined study values (P0, P2) and related library values (L1-L5) 3) Choose the applicable end points and have the study builder store them as part of the study design 4) If there are no previously linked end points for the objective that match my need, then the study builder will display all end points and let author pick one(s) relevant for my objective 5) After selection of study end points, for each end point prompt the author to optionally enter the timepoint(s) So that my protocol content is based on pre-defined library elements and has defined time points	A Study Designer user story
P4	As an author I want the mandatory study design elements to be included for my study based on the study level values selected and protocol level content so that all mandatory study design elements are included in each complete study design.	A Study Designer user story
P5	As an Author I want to study builder to derive a schedule to mimic the example below using provided mock data	A Study Designer user story
P6	As an author I want to be able to have the ability to set the status of a study design to APPROVED. Upon changing the status to approved, the content of that study design is locked down and can no longer be edited. Upon changing the status to approve the study design get the version name of “VERSION n” where n will equal the number of versions approved. Once approved, I now have a new action button available to start a new version. When startinga new version that defaults to DRAFT status, user has ability to select which prior approved study design version.	A Study Designer user story

JIRA

General

This section lists the comments made within the JIRA system on the user stories.

Ref	Text	Resolution
DDF-170	As a Librarian, I want to save my work as 'draft' so that I can complete my work over multiple endeavors. I want to be able to delete my draft if I no longer chose to create it. As an Author (of a study), I want to save my work as 'draft' so that I can complete my work over multiple endeavors. I want to be able to delete my draft if I no longer chose to create it.	A Metadata Repository user story. No further action as not in scope.
DDF-171	As a user, I want to the ability to choose whether to include all inactive elements or exclude inactive elements in a report.	A Metadata Repository user story. No further action as not in scope.
DDF-172	As a Librarian, I want to perform impact assessments when making any changes to approved versions.	A Metadata Repository user story. No further action as not in scope.
DDF-173	As an author (of a study), I want the ability to have clear visibility of changes between any two versions.	A Study Designer user story. No further action as not in scope.
DDF-174	As a user, I want to be able to upload/import content, e.g., large valid value lists, etc.	A Metadata Repository user story. No further action as not in scope.
DDF-175	As a user, I want to be able to search and view objects and relationships between objects	A Metadata Repository user story. No further action as not in scope.
DDF-176	User Story L1: As a Librarian, I want to be able to perform bulk active/inactivate reference library study design element(s) and all associated attributes, i.e., not forced to select one at a time as active or inactive.	A Metadata Repository user story. No further action as not in scope.
DDF-183	The librarian user stories now aim at functionalities of study builders and/or users of these systems. However the users of the USDM are the upstream and downstream systems and not directly the users of those systems. So search and add/remove functions like described in user story L1 to L5 are not directly applicable to the USDM and RA. However, the data structure must make	Done. Resolved by this document.

	it possible for the upstream system to provide this functionality. So a logical data structure and API requests are in scope. Can the user stories be adjusted to reflect this?	
DDF-184	As an upstream system I should be able to map all relevant protocol content to the USDM data model to be able to share this information via the SDR with other systems. As an upstream system I should be able to provide all USDM mapped protocol content via the API to the SDR or other compatible systems. As an downstream system I should be able to retrieve all relevant study information (and not more) and map it to my internal data structures.	Done. Resolved by this document.
DDF-188	User Story #13/User Story P5 may be missing info- there is a reference to below. In the "User Story" Column, it states, "As an Author I want to study builder to derive a schedule to mimic the example below using provided mock data." There is no example (at least that I can see).	Not a DDF related user story. Not in scope.