

Introduction



Problem Statement

- Inadequate test cases to fully test coding assumptions upfront
- Inadequate coding / lack of robustness of code
- Code re-work / updates during re-delivery cycles
- Delayed time to stable code

Solution

- Develop solid logical test cases before coding commences

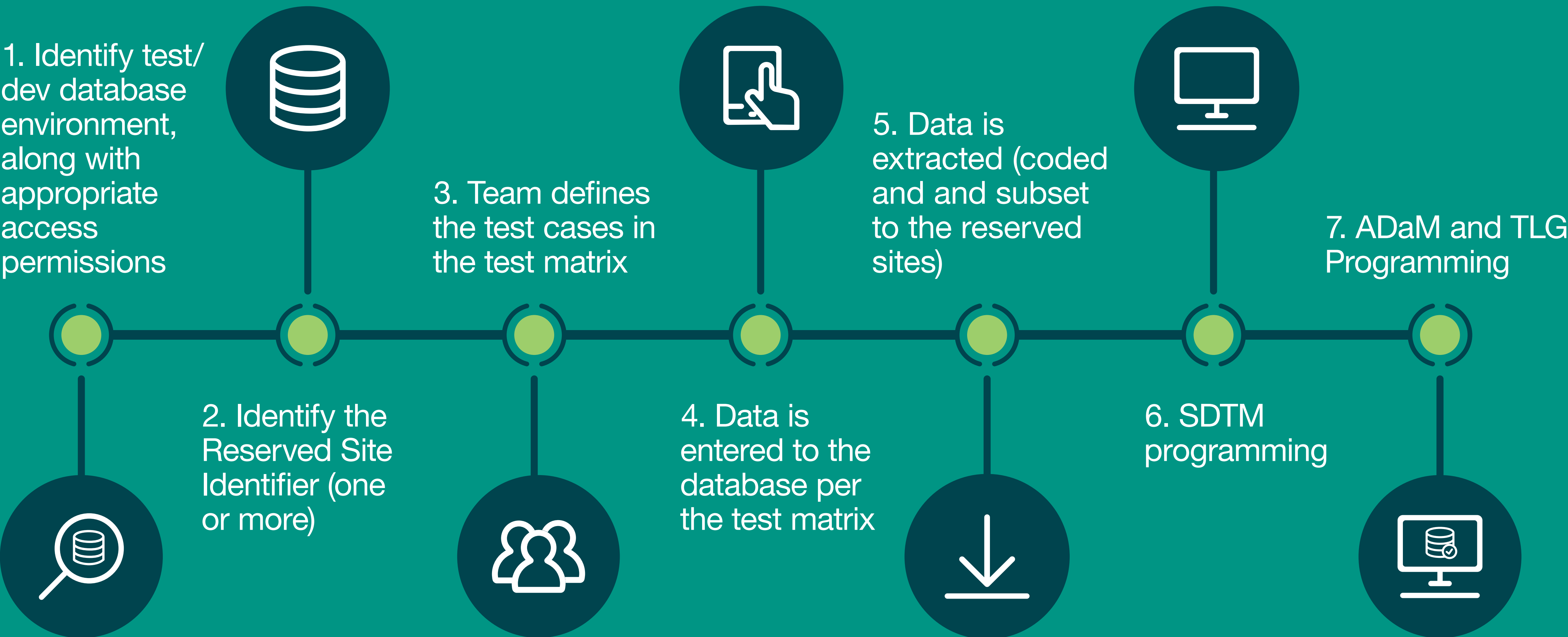
Return on Investment

- Increase robustness of code
- Reduction in re-work time
- Programming can start earlier

Process

Prerequisites

- Final Study Protocol
- Final approved CRF version
- Final Annotated (database annotations) CRF
- Final Database Specifications
- Other associated guidelines e.g. CRF completion guidelines



Example

Sponsor Name	Sponsor 1
ICON study Number	1234/5678
EDC System	Rave
Test Environment	TRAIN
Reserved Test Site (test database only)	T1235
Number of Subjects	10
Test Case 1	12351001 (Completed)
Test Case 2	12351002 (Screen Failure)
Test Case 3	12351003 (Screen Failure)
Test Case 4	12351004 (Screen Failure)
Test Case 5	12351005 (Discontinued)
Test Case 6	12351006 (Enrolled)
Test Case 7	12351007 (Completed Study)

FORM		Demographics						
Dataset Name	DM_GEN_U01		M_BIRTHDAT	DV_AGE	DV_AGEU	AGE	AGEU	M_SEX
Subject ID	Visit Name/ Folder Name	Visit date	What is the subjects date of birth?	Derived Age	Derived Age Unit	If complete birthdate is not provided, enter age at time of informed consent	Age Unit	What is the sex of the subject?
12351001	SCREENING	01-Jan-14	10-Jun-78	Derived	Derived	-	-	Female
12351002	SCREENING	01-Jan-16	UN-LINK-1965	Derived	Derived	54	Years	Male
12351003	SCREENING	01-Mar-17	UN-Mar-1972	Derived	Derived	45	Years	Male
12351004	SCREENING	-	-	-	-	42	-	Female
12351005	SCREENING	01-Jan-17	05-Nov-82	Derived	Derived	-	-	Male
12351006	SCREENING (test database only)	01-Jan-17	-	Derived	Derived	25	Years	Female

Considerations

There is an art to defining good test cases

- keep focus on the goal i.e. robust programs, less re-work
- avoid introducing illogical test cases that ‘break’ the programs or cause unnecessary ‘coding-around’
- but do give consideration to logical test cases, that may not be per protocol or deviate from the eCRF completion guidelines

Assess investment versus benefit to the study

- this process may benefit studies with a first reporting event after a small number of subjects are enrolled
 - but may not be of benefit for studies with more generous time to the first reporting event
- If beneficial, start the process as soon as perquisites are in place
- cross functional team should meet to discuss plans and test cases as soon as possible around eCRF live
 - define and enter the test data available at the same time as the SDTM specification is being written and finalized



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