

# How to build an IBDIS eCRF

– A timesaving and cost-effective solution for an important task

## Background

Electronic case report forms are demanded and well accepted tools by the scientific community. Facing, that team members very often work at different locations, speaking different languages or use different definitions and standards there is an increasing need for a **standardized, validated, easy-to-use, platform independent and cost-effective** software solution.

### eCRF Features

- Easy and cost-effective data capture systems
- Web technologies guarantee platform independence
- Highest security standards
- Validated matrix of Rights and Roles
- High quality of data with integrated consistency checks
- Easy-to-use query management tool

Based on the experience in technical, organisational and clinical issues, IBDIS has developed a checklist which guides through the procedure of planning, building and running an eCRF (according to the V-model of software development (Figure 1)).

### Step 1 What the investigator wants

The basis document of each eCRF is called user requirement specifications document URS. It includes a comprehensive description of the study, the list of participating centres, definitions of users and administrators, the scientific project team, a study flow chart, questionnaires if applicable, definition of laboratory values with units and ranges and a basic description of data management. In most cases the **study protocol** gives a perfect overview and detailed information about these themes. The author of the URS document is the principal investigator.

### Step 2 The technician's point of view

This document is called functional specifications document FS. It is a technical guide for the software development process and lists all entities and objects, their active and passive properties, all procedures, methods

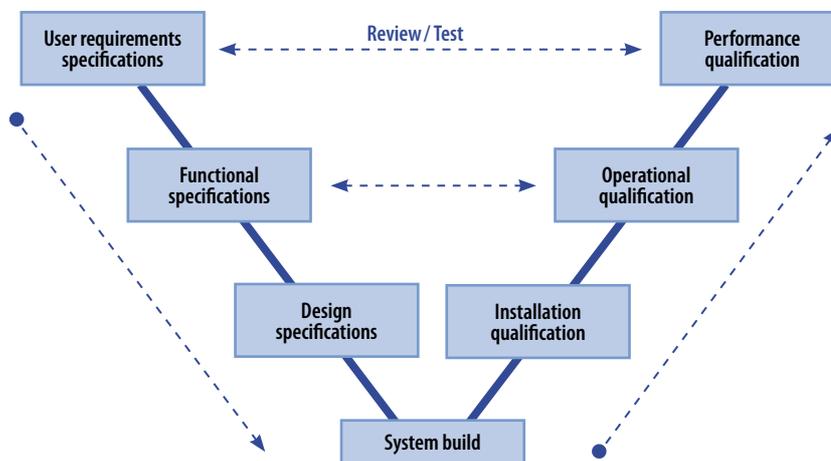


Figure 1. V-model of software development.

and functions which apply to them like listing, sorting or calculating. Functional specifications documents aim at structuring the contents of the URS by **grouping, standardizing, specifying, normalizing or simplifying**. This is accomplished by the IT experts of IBDIS.

### Step 3 How the software will look like and how it will interact with the user

The user interface is a critical object and very important for acceptance by the user. At this stage, the final technical and graphical design is defined. The design specification document DS gives an unambiguous and comprehensive view to the resulting software application, how it looks like and how it works. DS is a result of summarizing the URS and FS contents and is treated as a **guideline** and operating manual for the IBDIS technicians.

### Step 4 Building the software and database environment

This process is done by IBDIS software developers. Standard operating procedures SOPs guarantee **methodical, correct and traceable** software coding processes and stable database management systems. During this step the **first debugging** and testing actions are done.

### Step 5 Qualification processes

Installation qualification (IQ) establishes

that the software is coded as designed and specified, that it is properly installed in the selected environment, and that this environment is suitable for the operation and use of the application.

Operational or equipment qualification (OQ) is the process of demonstrating that the software will function according to its operational specification in the selected environment. Performance qualification (PQ) is the process of demonstrating that the software consistently performs according to the specification appropriate for its routine use.

### Go-Live

After finished all procedures of step 5 the eCRF software is marked with a version number and the code will be frozen. Then the IBDIS project manager, on behalf of the principal investigator, generates the access codes for all eCRF users.

### Shutdown

Closing the data capture system is a specified process in the lifecycle of an IBDIS eCRF and results in a structured, but revocable shutdown status.

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