

D3.3 Suite of patient and investigator facing software tools for data capture [Confidential Deliverable]

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Summary

The reference task incorporates development and implementation of interfaces and tools for web and/or mobile applications to be used by users (patients/investigators) to collect data via electronic Case Report Forms (eCRF) and electronic Clinical Outcome Assessments (eCOA). Data collected through these tools are core to the Mobilise-D tasks and stored on the data management platform - e-Science Central (e-SC), before relevant data is extracted and loaded into a Data Warehouse (DW).

The eCRFs are interfaced directly with e-SC APIs and tools to automatically exchange/collect the data. The eCOA data is uploaded through the e-SC portal by ERT on a scheduled basis. The requirements specifications for this suite of tools were drawn from the outputs of Task 3.1. The eCRF tool used in the Technical Validation Study (TVS) had some limitations and we took these learnings and feedback from users into consideration when designing the eCRF tool for the Clinical Validation Study (CVS). The new eCRF prototype is currently undergoing testing and any bugs identified are logged in Gitlab and addressed by the developer. This testing phase will be followed by training sessions with the site assessors. The eCOA suite used in the TVS will also be used in the CVS (although expanded due to number of sites and the number of instruments).

We have developed two types of tools:

- Tools for capturing eCRFs, developed by the University of Sheffield (USFD) and integrated into e-SC with the support of the University of Newcastle (UNEW) and University College Dublin (UCD)
- Tools for eCOAs developed by ERT with regular data extracts uploaded to eScience by ERT.

Each Section describes the two types of tools.