IDEA-FAST

Identifying Digital Endpoints to Assess FAtigue, Sleep and acTivities in daily living in Neurodegenerative disorders and Immune-mediated inflammatory diseases.

Grant Agreement No. 853981

WP2 – Clinical Knowledge and Insight

D2.6: Development of the final version of the electronic data capture system for the CVS

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Document History

Version	Date	Description
V0.1	05 May 2023	Initial draft
V0.2	12 May 2023	Addition of screenshots & minor corrections
V1.0	17 May 2023	Final version

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1 Abstract

UCAM has developed the bespoke Clinical Database for data capture as required for the IDEA-FAST Clinical Validation Study (CVS) protocol as part of WP2. The clinical database was initially developed for the Feasibility Study (FS), but was further refined and updated in line with the CVS protocol. Data collected is transferred via an Application Programming Interface (API) to the Data Management Platform in collaboration with WP5.

2 Introduction

The aim of the work reported in this deliverable was to develop and build a robust Data Capture System (database) to collect all necessary participant information for the CVS protocol. Similarly to the FS, this included participant registration, clinical data collection in an electronic case report form (CRF) together with appropriate device information. Data collected on the clinical database would then be securely transferred to the Data Management Platform (DMP).

3 Clinical Database (Data Capture System) Development

The clinical database was initially established in September 2020 for the FS and data collection was overseen until the end of the FS (approximately August 2021). During the FS period several adjustments were made to the clinical database to ensure accurate data collection and clarity based on users review and feedback. UCAM further developed the clinical database functionalities to include an Application Programming Interface (API) linking with the device (WP3) information used within the FS to provide direct linkage. An additional API was developed in collaboration with WP5 to fully automate the data transfer process; from the clinical database to the DMP. This was initially hoped to be in use during the FS time period, but a manual process was required to enable this transfer.

The IDEA-FAST CVS database specification and full electronic case report forms (CRFs) were developed between UNEW and WP5/WP6/WP7 for the CVS clinical database, adapting the project from the FS database and fulfilling the requirements of the CVS protocol. These were the basis for the UCAM team to design, build and test, to ensure the correct clinical data would be collected for the study.

3.1 Specification and construction

IDEA-FAST CVS Clinical Database https://ideafastcos.azurewebsites.net is a public-facing secure website and a 2 Factor Authentication (2FA) is utilized when logging in to maintain and administer the resource group. The system has in place robust audit trails and is subject to frequent back up. Access to the database is role-based, each with appropriate permissions as required.

To ensure that the completed database met the requirements and needs of the CVS protocol, multiple rounds of iterative User Acceptance Testing (UAT) were undertaken. At each round of UAT any problems or issues were addressed and UAT was conducted again.

UCAM created a training version of the clinical database to allow new users to practice and gain confidence with using the database and its functionality in a secure area separate to the main clinical database.

3.2 Challenges

Due to several periods of conflicting workloads and resource issues, initially due to the Covid-19 Pandemic, the project encountered some unfortunate delays which have recurred during the lifecycle of the CVS. Specialist knowledge and skills have been required for the development of the database, and replacing key members of staff took a significant amount of time during this period. Prioritisation of IDEA-FAST over ongoing Covid projects has been difficult, but progress was made wherever possible.

3.3 Ongoing activities

Since the initial UCAM database go-live and during ongoing use of the database for study data collection, suggestions for improvements and corrections to issues have been found by users which are fed back to the UCAM team for review and fixes as required. Communication and meetings are held according to need within WP6 together with WP4 and WP5 ensuring oversight and progress is maintained. Further refinement to the APIs currently built will continue based on user feedback. Additional work includes improvements to the Monitor role functionality to enable issues to be raised within the database.

4 Conclusions

There have been significant challenges and delays to the development and set up of the clinical database for the IDEA-FAST CVS, but the key deliverable of a secure data capture system has been met and is fully operational. It is expected that further refinements may be required together with ongoing maintenance. Future work will include Monitor role functionality improvements and working with WP5 on including authentication from the DMP Authentication API.