PRECISE4Q

PREDICTIVE MODELLING IN STROKE

DELIVERABLE

Project Acronym: **Precise4Q**

Grant Agreement number: **777107**

Project Title: **Personalised Medicine by Predictive Modelling in Stroke for better Quality of Life**

D5.1 Electronic patient recorded outcome framework (ePRO)

Revision: 1.0

Authors and Contributors	Dietmar Frey (CUB), Vince Madai (CUB)			
Responsible Author	Dietmar Frey		**Email**	dietmar.frey@charite.de
	Beneficiary	CUB	**Phone**	+4930450560398

Revision History, Status, Abstract, Keywords, Statement of Originality

Project co-funded by the European Commission within **H2020-SC1-2016-2017/SC1-PM-17-2017**		
Dissemination Level		
PU	Public, fully open	X
CO	Confidential, restricted under conditions set out in Model Grant Agreement	
CI	Classified, information as referred to in Commission Decision 2001/844/EC	

Revision History

Revision	Date	Author	Organisation	Description
0.1	17.02.19	Dietmar Frey	CUB	First draft
0.2	08.03.19	Dietmar Frey	CUB	Iteration after input from CRU (Charité Research Unit)
0.3	11.03.2019	Vince Madai	CUB	Review and corrections
1.0	29.04.2019	Dietmar Frey	CUB	Final version

Date of delivery	Contractual:	30.04.2019	Actual:	30.04.2019
Status	final **x**/draft ☐			

Abstract (for dissemination)	This document presents the framework for an eCRF (electronic case report form), the framework of an ePRO (electronic patient reported outcome) allowing fine-meshed recording of outcome by research staff and by the patients, and the perspective need addressed by an user/patient app for longitudinal data collection from various sources (direct input, smartphones, wearables, third party devices).
Keywords	ePRO (electronic patient recorded outcome), eCRF (electronic case report forms), clinical trials, longitudinal data, UX/UI, app, prevention

Statement of originality

This deliverable contains original unpublished work except where clearly indicated otherwise. Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation or both.

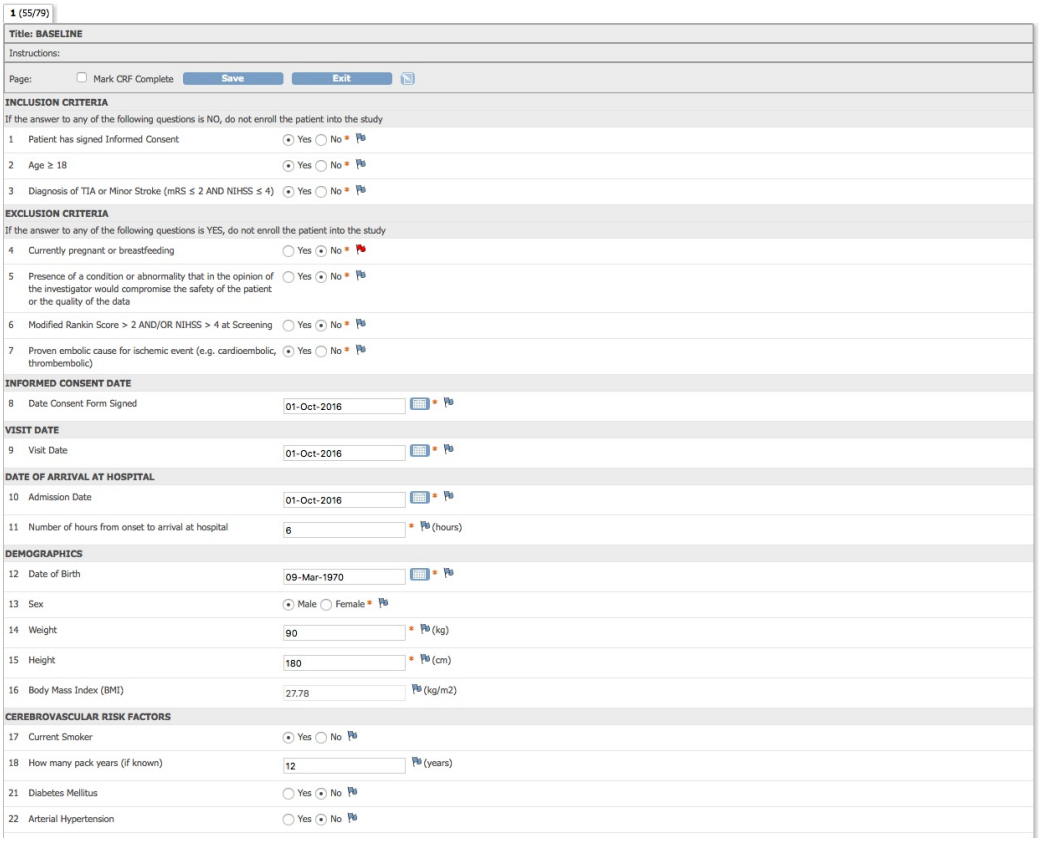
Table of content

1 Introduction

For both clinical prospective studies (Stroke treatment stage 2 and Stroke rehabilitation stage 3) obtaining follow-up information is crucial. Currently practised in most clinical studies, the gathering of the data is researcher-centred as data are collected top-down by the performing clinical staff. This is often inefficient and does not take into account patient motivation and often leads to high rates of "lost-to-follow-up". To facilitate the gathering of high quality data and at the same time ensure motivation and study compliance of patients, we are going to exploit end-user-based technologies to obtain patient-centred data. To this end we will develop an electronic case report form (eCRF) allowing fine-meshed recording of outcome by research staff. In addition, we seek to more involve the patient and implement an electronic patient recorded outcome framework (ePRO).
It is important to note, that this deliverable will focus on the set-up of the frameworks for the different needs and is for finalization and implementation dependent on the results of concomitant deliverables D5.2 and D5.4.

2 Electronic case record form (eCRF)

We have been designing and preparing an electronic case report form (eCRF) according to the potential and foreseeable needs set out in task 5.2 and delivered in the concomitant deliverable D5.2. The framework for this eCRF is ready to be iterated with the content to be delivered in D5.2. The same – designing and preparing the frameworks - applies for the stroke rehabilitation study (D5.4).
In figure 1 the first page of the baseline exam for the acute stroke study as in the eCRF is depicted. The framework is ready to use. Since the delivery date of both the study for acute stroke treatment (D5.2) and the study for rehabilitation and reintegration (D5.4) is the same as for this deliverable, changes are to be expected before study initiation.


1 (55/79)

Title: BASELINE

Instructions:

Page: Mark CRF Complete Save Exit

INCLUSION CRITERIA

If the answer to any of the following questions is NO, do not enroll the patient into the study

1	Patient has signed Informed Consent	Yes / No *
2	Age ≥ 18	Yes / No *
3	Diagnosis of TIA or Minor Stroke (mRS ≤ 2 AND NIHSS ≤ 4)	Yes / No *

EXCLUSION CRITERIA

If the answer to any of the following questions is YES, do not enroll the patient into the study

4	Currently pregnant or breastfeeding	Yes / No *
5	Presence of a condition or abnormality that in the opinion of the investigator would compromise the safety of the patient or the quality of the data	Yes / No *
6	Modified Rankin Score > 2 AND/OR NIHSS > 4 at Screening	Yes / No *
7	Proven embolic cause for ischemic event (e.g. cardioembolic, thrombembolic)	Yes / No *

INFORMED CONSENT DATE

8	Date Consent Form Signed	01-Oct-2016 *

VISIT DATE

9	Visit Date	01-Oct-2016 *

DATE OF ARRIVAL AT HOSPITAL

10	Admission Date	01-Oct-2016 *
11	Number of hours from onset to arrival at hospital	6 * (hours)

DEMOGRAPHICS

12	Date of Birth	09-Mar-1970 *
13	Sex	Male / Female *
14	Weight	90 * (kg)
15	Height	180 * (cm)
16	Body Mass Index (BMI)	27.78 (kg/m2)

CEREBROVASCULAR RISK FACTORS

17	Current Smoker	Yes / No
18	How many pack years (if known)	12 (years)
21	Diabetes Mellitus	Yes / No
22	Arterial Hypertension	Yes / No

Fig. 1: First page of baseline examination of acute stroke study (eCRF1)

3 Electronic patient-reported outcomes (ePRO)

For the build and implementation of the electronic patient-reported outcome (ePRO) the Charité as the responsible partner are already using the REDCap application framework for numerous studies and clinical trials. REDCap (Research Electronic Data Capture) is an easy-to-use web application for building and managing online surveys and databases.

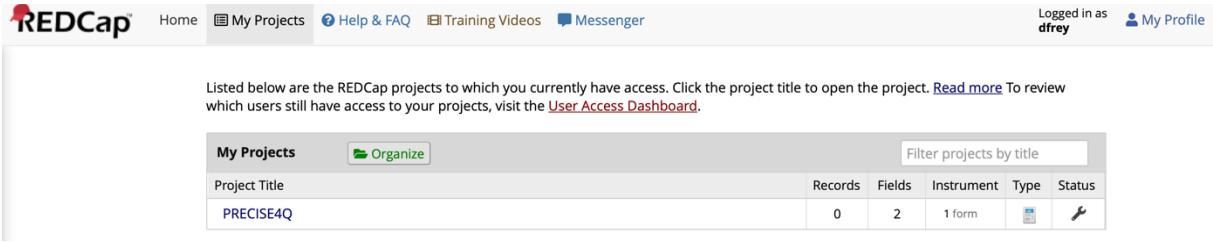


Fig. 2: Dedicated ePRO with the use of REDCap

Within the Charité (CUB) several large-scale projects have been successfully implemented by using REDCap. Building on the experience and knowledge of these successful research projects, PRECISE4Q will use the framework for longitudinal data collection by users and clinical staff alike. The framework is ready to be implemented after final decision and approval of the stroke treatment and rehabilitation/reintegration studies (D5.2 and D5.4), respectively.

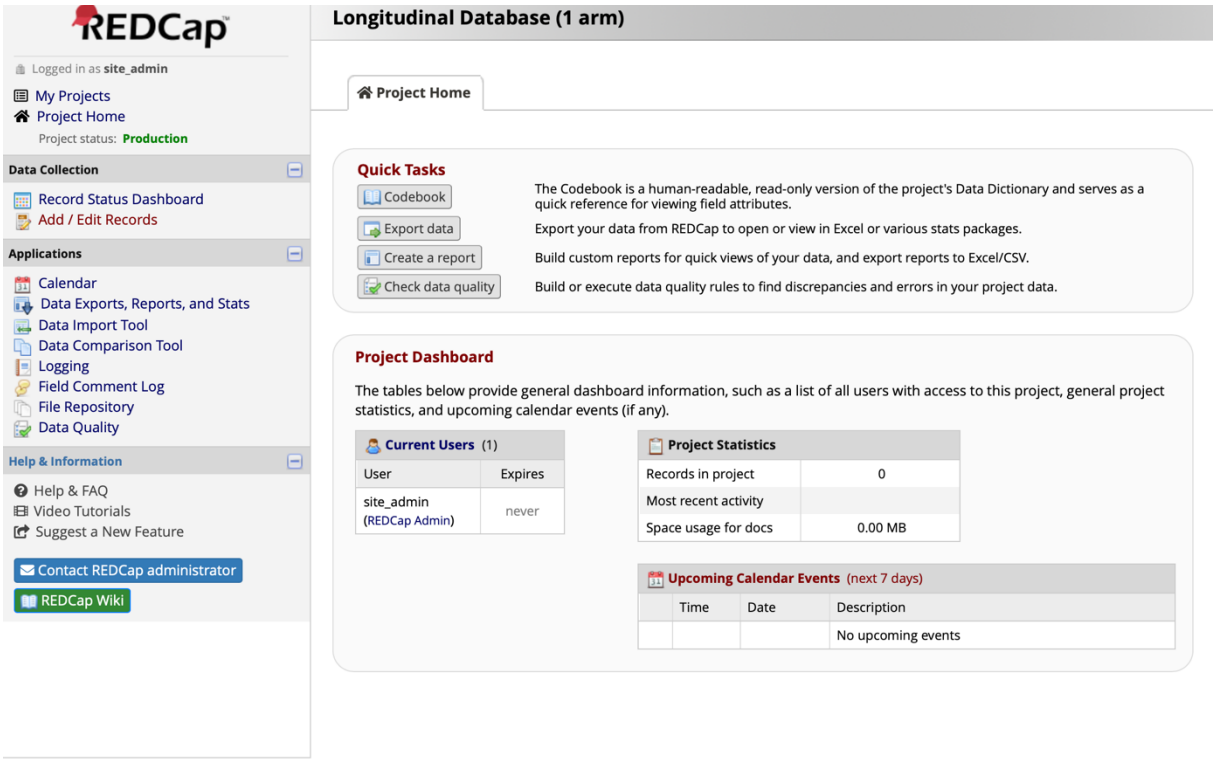


Fig. 3: REDCap project page for longitudinal database for PRECISE4Q

4 App-based follow-up

Complementing the above-mentioned frameworks, it might be necessary for a speedy and efficient conduction of follow-up that a user-centric and dedicated stroke app be provided for further data collection after dismissal of patients or even in a preventative approach. This would enable a higher yield of data and lower number lost to follow up. REDCap is a very powerful tool for implementation for patients in a clinical research environment but does not put its focus on usability and user experience for the customer, or patient. An easy-to-use tool is therefore warranted. By involving a strong partner with a ready-to-use patient app we could address the huge need of collecting longitudinal and high-granular data of individual patients. Various data sources such as direct input data, actively or passively recorded smartphone data, wearables data and data from third-party devices, can be integrated and be made available for further processing and analysis. This would not only enable us to train and test the machine learning models with previously unrecorded data but could potentially set a new standard for data quality and quantity in the out-patient ecosystem. Study onboarding and offboarding could easily be implemented and would enable researchers to have access to a large pool of data otherwise not accessible.

The decision how to involve a third party for the crucial collection of high risk patient data (primary and secondary prevention) will be taken after pending implementation of the electronic case report form framework and the electronic patient reported outcome framework. Both of these final implementations are subject to the concomitant delivered deliverables D5.2 (Study design for stroke treatment) and D5.4 (Study design rehabilitation/reintegration).

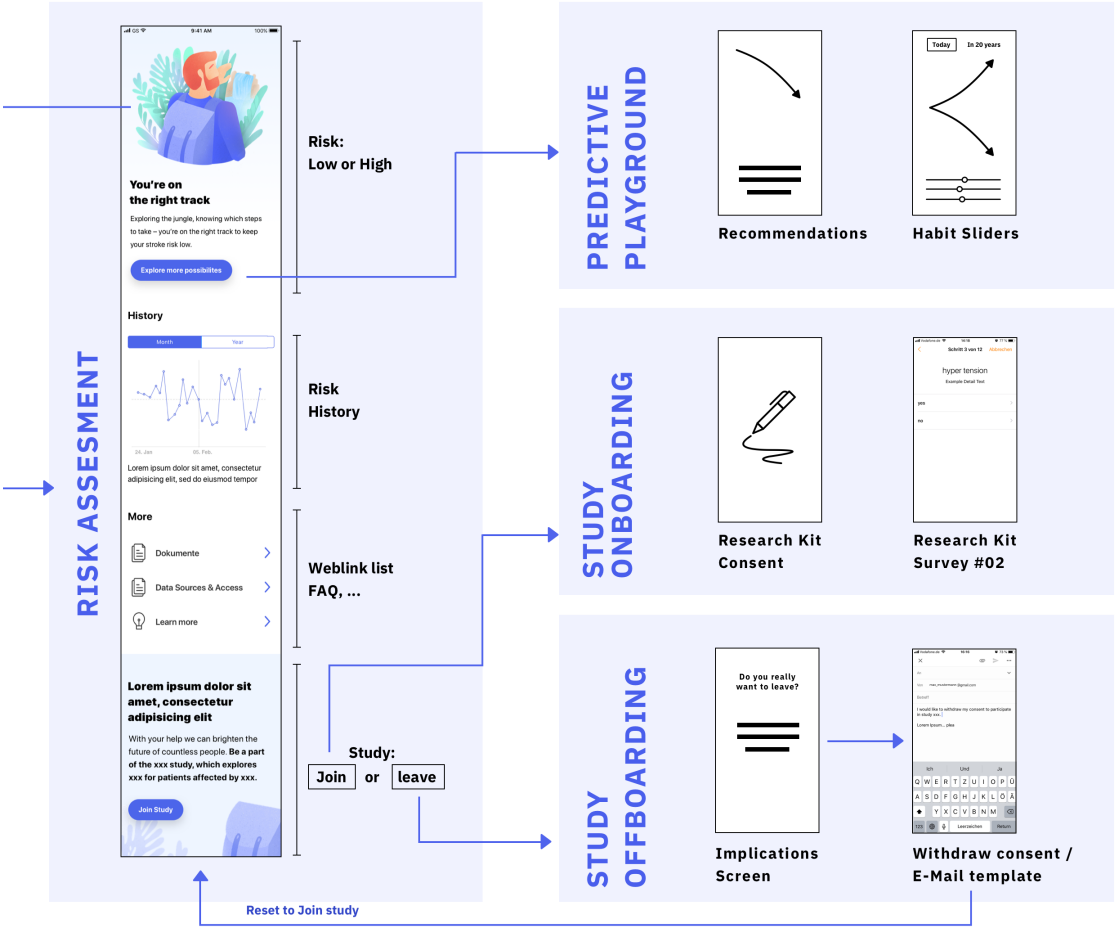


Fig. 4: Overview of patient app for risk assessment, and study implementation for data collection

5 Summary

We have set frameworks for electronic case report forms (eCRF) and electronic patient reported outcome (ePEO) for the planned prospective clinical studies for both acute treatment and stroke rehabilitation. The frameworks are ready to be implemented and are subject to changes in accordance with deliverables D5.2 and D5.4 that are both delivered at the same date as this Framework deliverable 5.1. Furthermore, for collection of additional data by the patient (smartphone-related, wearables, etc.), a third-party application (app) is planned to be involved in due time to achieve highest scientific and potentially commercial output for the overall success of PRECISE4Q.