GA N° 668353
H2020 Research and Innovation

Deliverable N°: D4.2
Title: Standardized Electronic Case Record Form (eCRF)

WP N° and Title**: WP4 - Clinical implementation and evaluation of pre-emptive PGx**
Lead beneficiary: **P1-LUMC**
Type: **Other**
Dissemination level: **Public**

Start date of project: 01/01/2016
Duration: 60 months

Due date of deliverable: Month 18
Actual submission date: 21/10/2016 (Month 10)

Comment: not applicable

Selection process for the eCRF

A market scan of available software packages identified 2 potential candidates. 1) ProMISe (Project Manager Internet Service; https://www.lumc.nl/org/msbi/research/adm/PromiseBasic/), and 2) CASTOR, https://castoredc.com/.

After thorough evaluation, ProMISe (Project Manager Internet Service) was selected as the most suitable eCRF software for the U-PGx PREPARE study. Reasons for this are 1) the ability of the database structure to be tailored to the needs of PREPARE, 2) the availability of data management and statistical expertise of ProMISe employees to support the database development and the data logistics, and 3) the compliance with international data-safety and privacy laws and GCP.

ProMISe is a web based relational database management system for the design, maintenance and use of (clinical) data management. This ProMISe system provides in custom made databases for scientific medical research as well as an application for on-line data entry, quality checks and reporting. It also provides a tool for data retrieval to facilitate statistical analysis. ProMISe has been applied successfully in many multi-center studies.

ProMISe is developed within the Leiden University Medical Center (LUMC) by Ronald Brand, professor of Good Research Datamanagement. Ronald Brand is head of the Section Advanced Data Management (ADM). ADM works in close collaboration with the statistical staff of the department of Biostatistics & BioInformatics. Collaboration with these experts will ensure the development of a user friendly eCRF which will enable smooth data collection and data extraction for the data analysis.

ADM is NEN7510 certified and ProMISe meets the requirements for data-safety and privacy set by international law. Due to this certification the ProMISe system facilitates the availability, integrity and confidentiality of your data. ProMISe facilitates you to store, exchange and retrieve data according to the security conditions demanded by GCP.

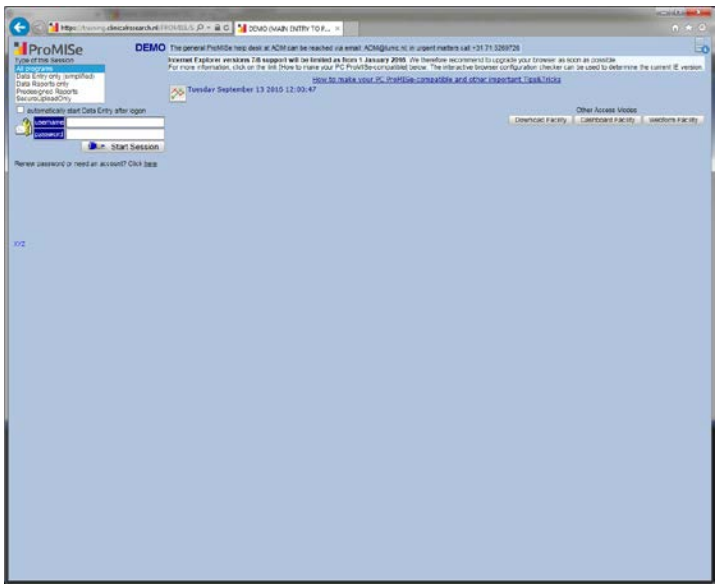

Figure 1: Log in page ProMISe

ProMISe will allow all PREPARE study personnel to log into the data entry portal, with their own

login and password (shown in Figure 1). See https://www.msbi.nl/promise/ProMISe.aspx for more information.

PREPARE eCRF Database Structure

The PREPARE eCRF database will be built in close collaboration with ADM data managers and the trial statistician to ensure a usable database once data collection is finalized.

The general structure of the database is shown in Figure 2. For each index drug a record is created and patient and other data are added. When a subsequent drug included in the PREPARE study is prescribed to a patient, the index drug record is duplicated and flagged as "subsequent drug".

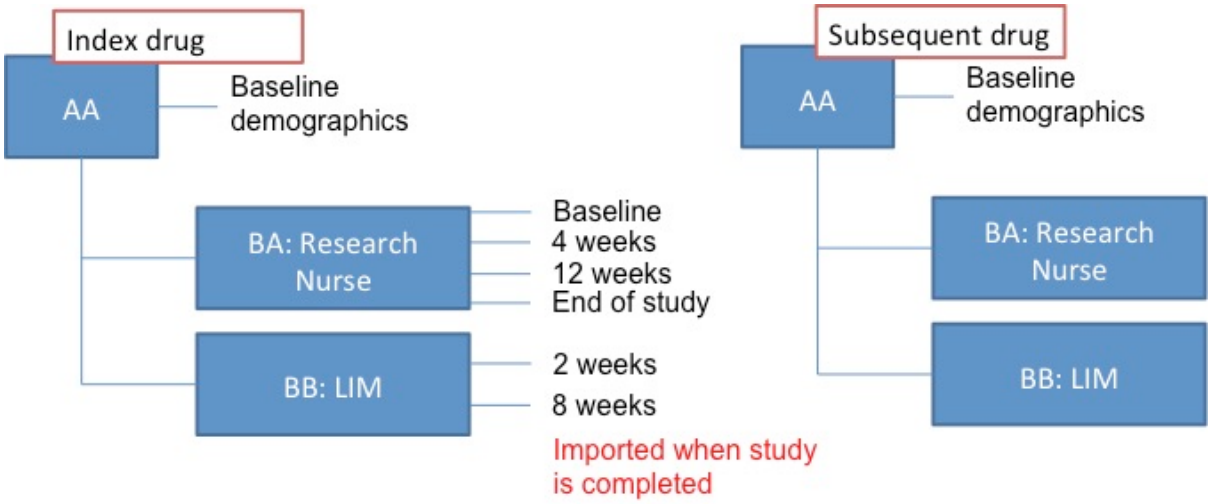

Figure 2: The general structure of the eCRF database AA includes baseline demographics used to give information about the sample population. BA and BB include repeated measures.

PREPARE – Lareb Intensive Monitoring (LIM) link

As part of the prepare project, patient reported outcome data will be collected with the online Lareb Intensive Monitoring tool. Data collected through the LIM system will be imported to the eCRF in ProMISe in bulk once the study is completed.

PREPARE eCRF

The PREPRARE eCRF consists of approximately 500 fields and contains the following chapters:

1. **[AA] Screening and index drug**
1.1. General information
1.2. Inclusion and exclusion criteria
1.3. Demographics
1.4. Recruitment information
1.5. Blood/Saliva sample collection
1.6. Pharmacogenomic testing results
1.7. Index drug
1.8. Adherence to DPWG guidelines (study arm only)
2. **[AA] Patient Demographics (can be updated during follow up at BL, week 4, 12 and end of study and during follow up of subsequent drugs)**
2.1 Previous and current medical history
2.2 Co-medication
2.3 Lab Biochemistry
2.4 Miscellaneous
3. **[BA] Research Nurse (at BL, 4 weeks, 8 weeks and end of study arm)**
3.1. General information (BL, 4 w, 12 w, end of study)
3.2. Index drug changes (4 w, 12 w, end of study)
3.3. (Index) drug adherence (4w, 12 w and end of study)
3.4. Global Health Score (PROMIS 10) (BL, 4 w, 12 w, end of study)
3.5. Adverse drug events(4 w, 12 w, end of study)
3.6. Lab biochemistry (4 w, 12 w, end of study)
3.7. Miscellaneous (4 w, 12 w, end of study)
3.8. Quality of Life (BL, 4 w, 12 w, end of study)
3.9. Healthcare costs (related to ADRs) (4 w, 12 w, end of study)
3.10. Attitudes and knowledge of PGx (BL and end of study)
3.11. Identifying extreme phenotype (4 w, 12 w, end of study)
3.12. Plasma blood samples (only for those included in the sub-study) (4 w, 12 w, end of study
3.13. Clinical data (only for those included in the sub-study) (4w, 12w and end of study)
4. **[BB] LIM (at 2 weeks and 8 weeks)**
4.1. General information
4.2. Patient Reported Adverse drug events
4.3. Healthcare costs
5. **Repeasted at all subsequent PGx drug prescriptions**
5.1. Contact information of HCP
5.2. Actionability
5.2 Index drug (as a subsequent prescription)
5.3 Adherence to DPWH guidelines (study arm only)
6. [AA] Trial Related Events
7. [AA] Subject withdrawal
8. [AA] Expenses and Case Report Form Sign-Off