Wrapper document for the joining of: Deliverable No. D6.2

Evaluation report of the usability of p-medicine tools within the ECRIN infrastructure

with

Deliverable No. D15.3

Certification criteria review and implementation

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Dissemination Level		
PU	Public	
PP	Restricted to other programme participants (including the Commission Services)	
RE	Restricted to a group specified by the consortium (including the Commission Services)	
CO	Confidential, only for members of the consortium (including the Commission Services)	X

SEVENTH FRAMEWORK PROGRAMME

COVER AND CONTROL PAGE OF DOCUMENT	
Project Acronym:	***p-medicine***
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ABSTRACT:

To be employed in personalised medicine clinical trials, p-medicine tools have to meet many requirements for usage in large, international GCP trials. Developers of p-medicine tools were surveyed to evaluate the usability of p-medicine tools using requirements for GCP compliance, quality management, sustainability / business plan and process conformance. Software maturity and gap analysis showed that considerable gaps exist and that the tools in the present state cannot be employed by ECRIN. The results of the gap analysis together with the technical specifications for usage in ECRIN and the requirements for GCP compliance were used for validation of p-medicine tools. Using specific check-lists and matrices each component within the p-medicine environment will be evaluated. Risk assessment matrices are provided so that the validation can be done risk-based. Because of the heterogeneity of maturity of different tools, this has to be done at different time points. After component developer have evaluate their components using the developed check-lists, found issues will be analysed and corrected. Iteratively the components will be re-evaluated until they fully comply with the criteria.

KEYWORD LIST: requirements, regulations, GCP, tools, quality management, agile development, data security, pseudonymization, system validation, evaluation, ECRIN

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[1] **R**=Report, **P**=Prototype, **D**=Demonstrator, **O**=Other

[2] **PU**=Public, **PP**=Restricted to other programme participants (including the Commission Services), **RE**=Restricted to a group specified by the consortium (including the Commission Services), **CO**=Confidential, only for members of the consortium (including the Commission Services)

1 Preamble

It was requested to consolidate Deliverables 15.3 and 6.2 relating to Tasks 15.4 and 6.2. The reason for consolidation is based on the fact that in p-medicine the evaluation of products for their valid use in clinical trials is performed twice: Firstly, as part of the quality management in work package 15 “Quality Assurance, Evaluation and Validation” and secondly, as part of the integration of p-medicine tools in a clinical research infrastructure in work package 6. In work task 15.4 a comprehensive survey is performed to discover all of the requirements which a software component has to fulfil in order for it to be lawfully employed in some clinical research setting. This activity resulted in a set of criteria based check-lists and matrices designed for evaluation of all software components. Subsequently, the developers are expected to iteratively re-evaluate their components on the basis of the check-lists.

In work task 6.2 requirements were developed and conform to regulations to be used in large, international clinical GCP [Good Clinical Practice] trials and to be integrated into existing systems of ECRIN. Thus, concepts required for data security, privacy, data quality and validation must be implemented. A tool development maturity and a requirements gap analysis were performed that gave much information how to improve the development process and to conduct system validation. This information can flow into the validation efforts of WT 15.4. Both tasks intend to ensure that the software being developed within the p-medicine project is in accordance with all regulatory and good practices and to enable its legitimate and compliant use in the settings of clinical trials.

Although, a software tool can be developed according to GCP requirements (e.g. audit trail, access controls, etc.), the GCP validation process must be conducted for the installation actually employed for a clinical trial by the tool user/customer. Part of the validation process conducted by the tool user is a developer assessment. For this task, Del. 6.2 developed recommendations to prepare p-medicine developers for their assessment by improving quality management.

Dependency matrix

Del6.2	**Del15.3**
Assessment of tool maturity (3.1)	Assessment of tool maturity, has to be done regularly Tools have to be prepared for integration
Questionnaire for the p-medicine business model (3.3.1)	The business model has to be further fleshed out
Questionnaire tool development requirements for the developer (QA, GCP) (3.3.2)	Results of gap analysis used for validation impact assessment
Requirements for a CDMS / EDC system for data collection in GCP compliant clinical (ObTiMA) (3.3.3)	Results of gap analysis used for validation impact assessment
Requirements for a tool to support biobanking in clinical trials (Biomaterial Manager) (3.3.4)	
Requirements for the evaluation of Dr.Eye for clinical trials usage (3.3.5)	
Risk assessment for GCP compliance of Portal	Results of risk analysis used for validation impact assessment

Risk assessment for GCP compliance of ObTiMA	Results of risk analysis used for validation impact assessment
Risk assessment of OA	Results of risk analysis used for validation impact assessment
Recommendations	Recommendations used for validation preparation