Blueprint for Harmonizing Non-Standardized Disease Registries to Allow Federated Analysis – prepare for the future

ONLINE REPOSITORY APPENDIX

Content

Table E1. Estimation of the time required for building a FAP

Topic	Tasks	Estimated average time needed
Basic conditions	Setting-up a collaboration network/consortium - Writing of a protocol and governance document - Selection of a legal body (foundation/society) for a clinical research collaboration - Securing of sufficient financial resources for ≥3 years - Appointment of a full-time dedicated project manager	10 months
	- Establishment of a contract with an SME specializing in OHDSI, OMOP CDM and mapping - Establishment of contract with a hands-on statistician with programming skills - Written confirmation from each registry that patients have given written consent to use their medical data for (international) clinical research - Identification for each local registry of named individuals in the following roles: - Registry owner - Legal officer - Clinical expert - Source data expert - IT contact/administrator - Translator of medical terminology - Platform/System user - Conclusion of collaboration agreements between CRC and registries	8 months
Conceptual aspects	- Production of documents and a Power Point presentation explaining the OMOP CDM and the federated approach to all stakeholders - Organization of a plenary kick-off meeting with all stakeholders	3 months
	- Organization of regular team meetings for each registry to monitor progress	Per registry 2h/week
Technical aspects	- Provision/hire of a dedicated Linux server for each registry (local data centre or cloud environment) for the installation and setup of the FAP, with access to a local copy of the source database;	Per registry 2 months

	- Provision to all required parties of access to the Linux registry servers - Testing of the functioning of the FAP on local Linux servers by SME	
Mapping aspects	- Checks source data quality - Provision of registry data dictionary to SME by source data experts - Provision of a representative, but anonymized registry data sample by local team to smoothen ETL process and avoid "black box mapping" - Assistance by clinical experts in optimizing the mapping - Provision by SME to statistician(s) of a codebook of the variables mapped	Per registry 3 months
Analytical aspects and Quality control	- Learning by statistician(s) on the principles of OHDSI and OMOP common data model - Provision by SME of access to FAP for statistician(s) - Creation by statistician of scripts in R (or OHDSI tools for the production of descriptive summary statistics	1 month
	- Execution by local analyst in each country of the pre-written Rscript via the FAP - Checks by clinical on the validity of the output and provision of feedback to statistician and SME Revision by source data expert and SME of any mapping issues. - Creation of a second round of data summaries and a repeat of the quality control process - Production of final OMOP CDM tables	Per registry 3 months
Research studies	- Creation of research protocol and approval by CRC, local clinical experts and registry owners - Identification of dedicated local teams for each registry, comprising clinical experts, source data experts and data analysts. - Creation of a formal analysis plan by a statistician, for review and approval by representatives of all participating registries - Creation by statistician of analysis scripts in R (or OHDSI tools)	Depending the magnitude and complexity of the study ≥6 months

Table E2. Countries engaged in SHARP CRC and their registry's status for the SHARP FAP

SHARP Countries	Registry Name	Status: Connexion to SHARP FAP	Comments
Austria	ASA-Net: Austria Severe Asthma Net	Not Connected	Under communication to integrate SHARP Central Registry
Belgium	BSAR: Belgium Severe Asthma Registry	Connected	
Croatia	SHARP Central	Connected	
Czech Republic	GAN: German Asthma Network	Connected	
Denmark	DSAR: Danish Severe Asthma Registry	Connection ongoing	
Estonia	SHARP Central	Connected	
Finland		Not Connected	Under communication to integrate the FAP
France	RAMSES: The French registry of severe asthma patients	Connected	
Germany	GAN	Connected	
Greece	HTS-SAR: Hellenic Thoracic Society - Severe Asthma Registry	Connected	
Hungary	SHARP Central	Connected	
Iceland		Not Connected	Under communication to integrate the FAP
Ireland	SHARP Central	Connection ongoing	
Italy	SANI: Severe Asthma Network Italy	Connected	
Latvia	SHARP Central	Connected	
Lithuania	SHARP Central	Connected	
Netherlands	RAPSODI/SHARP Central	Connected	
Poland	SHARP Central	Connected	

Portugal	RAG: Registo de Asma Grave Portugal	Connected	
Romania	SHARP Central	Connected	
Russia		Not Connected	Russian Pulmonary society declined the invite to the SHARP FAP
Serbia	SHARP Central	Connected	
Slovenia	SHARP Central	Connected	
Spain	GEMA: Spanish Asthma Guidelines	Connected	
Sweden	SHARP Central	Connected	
Switzerland	GAN	Connected	
Turkey	SHARP Central	Connected	
United Kingdom	UKSAR: UK Severe Asthma Registry	Connection ongoing	

Figure E1. Pie Chart and time required for building a FAP plus proof of principle study