UPDATE OF THE EARLY DEMAND MAP FOR THE PUBLIC INNOVATION PURCHASE OF THE MedeA PROJECT (PUBLISHED IN APRIL 2019).

NOTE: Corresponds to Former Challenge 4 on the Initial Early Demand Map (April 2019).

CHALLENGE 3: DEVELOPMENT OF ASSESSMENT SYSTEMS FOR PATIENTS AND/OR HEALTHY VOLUNTEERS PARTICIPATING IN CLINICAL TRIALS		[PePS:EMC-SeBIO-SeOM]
NEED	**DESCRIPTION**	**PROCEDURE TO FOLLOW**
It is required to develop a tool to optimize the selection/stratification of healthy volunteers/patients participating in Bioequivalence Studies and Clinical Trials (ECCT) from the optimization of the pre-screening system, from implementing biomarkers of different types, pharmacokinetic and pharmacodynamic. • From the healthcare point of view, it is essential to generate an assistance model that stratifies/personalizes not only prescription but also clinical research, with its corresponding tools in parallel to the PoPS generated in Lot 1. • At the pharmacokinetic level it is necessary to generate a prediction model of the metabolic phenotype based on the genotype, for this it is necessary to study the phenotype and genotyping of healthy volunteers, or use another methodology. This system will prevent pharmacokinetic interactions and help in the selection of healthy volunteers and patients in clinical studies. • At the pharmacodynamic level, in the context of the clinical research process, the use of genetic biomarkers will be essential, which will allow the generation of drugs for groups of patients (stratification) or, in particular cases, individualization, especially in oncology, where somatic genetic polymorphisms will have to be integrated with germline polymorphisms.	Development of an innovative clinical decision support system with visualization tool (CDSS-CDVT) for pharmacogenetic evaluation in the context of clinical research, to optimize the selection of healthy volunteers/patients in the pre-screening phase in order to reduce risks (evaluation of potential drug interactions and incorporation of therapeutic target variables) and potentially pharmacodynamic. • The aim is to have an automated system (CDSS-CVT) for participant selection (PePS, "Personalized Stratification System") in clinical research that considers pharmacogenetic variables, optimizes the metabolic phenotype/genotype relationship, and values potential pharmacological and pharmacodynamic interactions. • At the pharmacokinetic level, it is proposed to determine the relationship between genotype(s)-metabolic phenotype(s), following different methodologies, as well as the determination and evaluation of metabolic indices based on the test drug(s) used and/or indices based on endogenous compounds and their relationship with phenotypes based on genotype. With this information, a tool can be built to calculate the Computational Metabolic Endophenotype (**MME**), essential for the development of the Stratification System of Healthy Volunteers and Patients participating in Bioequivalence Studies and Phase I Clinical Trials. • Generation of a CDSS tool that applies the EMC to bioequivalence studies in Healthy Volunteers (**SeBIO**). • Generation of a CDSS tool for stratification in oncology that integrates pharmacokinetic variables and tumor-related polymorphisms (**SeOM**). **Development of PePS (including EMC-Metabolic genotype-phenotype relationship, applied to bioequivalence studies Se BIO and Oncology -SeOM-).** **Corresponds to Former Challenge 4 on the Initial Early Demand Map (April 2019).**	Innovative Public Procurement / Innovation Partnership

Budget available Challenge 3: **631,354 €.**
Maximum budget to be awarded per company in Phase I (VAT included): **420,902.52 €.**