



Discussion on additional RITA CDEs

In April 2023, the RITA registry owners were invited to participate to an online survey using the consensus formation technique (Delphi and Nominal Group Technique), to **define domain specific common data elements (DCDEs) related to immune disorders** for the Common Data Dictionary in addition to the CDE already proposed by the JRC.

The participants were asked to list which variables they considered to be essential for research in the field of Rare Immunological Disorders and which should therefore be included in the core-set variables for RIDs.

All types of variables could be included: signs, symptoms, laboratory tests.

Out of 49 Registry owners invited, 24 replied and participated to the survey, proposing additional data elements to be considered.

Already in this initial phase it started to be suggested that the definition of CDEs that will be common to all conditions would be extremely difficult, due to the great disease specificity among the diseases covered by RITA.

The survey results were analysed and processed by the MeRITA coordination team, in order to exclude those already identified by JRC and to group them into the following categories:

- Clinical
- Immunological
- Complications
- Disease activity
- Serological
- Drugs
- Imaging
- General

And then underwent a further division into parameters that could be considered common to all the diseases or disease specific.

During the MeRITA Final Meeting, such results were shared and discussed with Registry owners and ERN members. It was agreed unanimously that the element contained in the CDE of JRC could be presently considered sufficient for the general purpose of reaching an overall picture of patients with conditions covered by ERN RITA.

The number of variables at functional, genetic, epigenetic and serological levels to add would be extremely high, cumbersome and their inclusion into to the CDEs list time consuming too complex the related data collection from so many different data sources.