**European Joint Programme on Rare Diseases**

**(EJP RD)**

**1st Internal Call for Proposals**

**"Demonstration projects** **on existing statistical methodologies to improve RD clinical trials”**

**1-pager proposal form**

**All fields must be completed using "Arial font, size 11" characters, single-spaced, margins of 1.27 cm.**

**Please note that incomplete 1-pager proposals, proposals using a different format or exceeding length limitations of any section will be rejected without further review.**

All the information requested in this document must be **compiled into one single PDF-document** andthe proposals **should be send to the call secretariat** of the EJP RD **by March 15, 2020**, on the following email address

demonstration.callsec@ejprarediseases.org

**All headings and all subpoints in the section “Data description” need to be addressed and clearly indicated**

**Basic project data**

**Project Coordinator:**

|  |  |
| --- | --- |
| **Family Name, first Name** |  |
| **Institution/Department** |  |
| **Department** |  |
| **Position** |  |
| **Address** |  |
| **Zip code, City Country** |  |
| **Phone + Fax** |  |
| **E-mail address** |  |
| **Type of entity** | Academia, Clinical or Public Health |
| **Type of entity (public/private-for-profit/private-non-for-profit)** |  |

**Signature of the Project Coordinator**

**Project Coordinator:**

Name, Institution

Place, Date, Signature

**To assist in the choice of suitable methodology area described in the call section 4.3. Table 1, please indicate at least one of the following topics that might be suitable for your data (in your opinion).**

|  |
| --- |
| Uncertainty evaluation  Primary outcome variable (surrogate)  Primary outcome variable (Co-primary)  Use of external information (historical control)  Use of external information (extrapolation)  Use of external information (dose response profiles) |
| Use of external information (single arm trials  - threshold crossing)  n-of-1 trials  Rigorous use of longitudinal information, linked to an  existing clinical trials dataset for a specific rare  disease |

**Data description** (max. 1 page)

**Description of the following:**

**a. Data structure (including individual patient data, type of data [binary/continuous], outcome variables),**

**b. Study design (including number of treatment groups, parallel group / crossover / n-of-1 trials),**

**c. Available information, which was gathered outside of the respective clinical trial (external information) but might be useful to support the evidence of the respective clinical trial.**

**Please answer the points a.-c. as specific as possible.**

|  |
| --- |
|  |