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**Application to access the Central Data Analyser (Collecteur Analyseur de Données - CAD) for the reuse of PFMG2025 data in** **research projects**

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| **Title of the research project:** |  |
| **Coordinator of the research project:** |  |
| **Structure with which the coordinator is affiliated:** |  |
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| **Summary of the research project** (max. 2,000 characters, including spaces) | |
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**Summary of the research project in language understandable to all. This will be posted on the PFMG2025 website if the access request is accepted.** (Max. 2000 characters including spaces)

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**1. Presentation of the research project** [MAX. 3 PAGES]

**1.1. Context and rationale for the research project**

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| **1.2. Objectives of the research project** |  |
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| **1.3. Objectives of the part of the research project for which reuse of a PFMG2025 data set is requested** | |
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**2. Presentation of the teams**

**2.1. Presentation of the teams associated with the research project** [MAX. 10 LINES PER TEAM]

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| **2.2. Data analysis expertise** [MAX. 1 PAGE]   * *profiles of the team members responsible for data analysis* * *their previous experience in data analysis* * *number of full-time equivalents (FTEs)* |
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**3. Data required for the research project**

**3.1. PFMG2025 data set required for the research project** [MAX. 1 PAGE]

**3.1.1. Description of the PFMG2025 data set required for the research project**

* *data collected as part of the healthcare (pre-indication(s)) and/or pilot project(s)*
* *description of the study population, characteristics of the subjects*
* *number of subjects*
* *format required for the genomic data (vcf, BAM, etc.)* *and justification of the required formats*
* *details of the clinical data*
* *if applicable, group of control individuals for the research project (characteristics of the individuals and number of subjects required)*

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| ***3.1.2.* Relevance of the PFMG2025 data set to the research project**   * *added value represented by the PFMG2025 data set for the research project* * *rationale for the number of subjects required* |  |
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| **3.2. If applicable, description of the research team's data sets outside PFMG2025 to be imported into the CAD** [MAX. 1 PAGE]   * *description of the study population, characteristics of the subjects* * *description of the source databases of the data sets (clinical trial, cohort, healthcare data, etc.)* * *data type (omics, clinical, etc.)* * *data volume* * *level of data structuring* * *number of subjects* * *state the storage location and recommended arrangements (hosting, duration, access conditions)* | |
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***3.3.* If applicable, description of the public data sets to be imported into the CAD** [MAX. 1 PAGE]

* *description of the study population, characteristics of the subjects*
* *description of the source databases of the data sets (clinical trial, cohort, healthcare data...)*
* *data type (omics, clinical, etc.)*
* *data volume*
* *level of data structuring*
* *number of subjects*
* *state the storage location and recommended arrangements (hosting, duration, access conditions)*

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| ***3.4.* If applicable, description of the data sets used in the project that will remain outside of the CAD (federated approach with the CAD)** [MAX. 1 PAGE]   * *description of the study population, characteristics of the subjects* * *description of the source databases of the data sets (clinical trial, cohort, healthcare data, etc.)* * *data type (omics, clinical, etc.)* * *data volume* * *level of data structuring* * *number of subjects* * *state the storage location and recommended arrangements (hosting, duration, access conditions)*  |  |  | | --- | --- | |  |  |   **3.5. If applicable, description of the needs in terms of pairing of the PFMG2025 data set with non-PFMG2025 data sets** [MAX. 1 PAGE] | |
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| **3.6. If applicable, description of the needs in terms of subject re-identification** [MAX. 1 PAGE] | |
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**4. Data analysis in the CAD**

**4.1. Methods of analysis** [MAX. 1 PAGE]

*The analysis methods envisaged must be clearly described and not just listed.*

* *description of the proposed methodology (It can also be presented in the form of a captioned diagram rather than text.)*
* *planned statistical analyses*
* *justification of the necessary statistical power, suitability of the methodology with the requested data*

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| **4.2. Analysis tools used for the project**  **4.2.1. Expression of needs for tools present in the CAD** | |
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| **4.2.2. Additional tools to import into the secure area reserved for the project**  ***Note:*** *Tools within the secure area will not be able to communicate with the internet. If so, they will need to be adapted accordingly.* | |
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| **4.3. CAD calculation capacity required for data analysis**  *- Number of CPU*  *- Required RAM space (number of gigabytes)* | |
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| **4.4. Storage space required for external data (from the research team and/or external) to be imported into the CAD** |
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| **4.5. Duration of the analysis (duration of opening of the secure area reserved for the project)** |
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| **4.6. If applicable, request for CAD assistance with data analysis**  *- presentation and definition of needs* |
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**5. Description of the data that will come out of the secure area after conducting the analysis in the CAD (results of the analysis)** [MAX. 1 PAGE]

* *level of sensitivity of the data constituted by the results of the analysis in the CAD*
* *arrangements for hosting the data constituted by the results of the analysis in the CAD*

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|  | **6. Compliance with GDPR** [MAX. 1 PAGE] |  |
|  | **6.1. Regulatory procedures for the research project** |  |
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|  | **6.2. Regulatory compliance of the non-PFMG2025 data collections that will be analysed in the CAD** | |
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|  | **7. Provisional schedule** [MAX. 1 PAGE] |  |
|  | **7.1. Provisional schedule for obtaining funding for the research project** |  |
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|  | **7.2. Provisional schedule for obtaining regulatory approvals for the research project** | |
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| **7.3. Provisional date of access to the PFMG2025 data** | | | | |
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| **7.4. Envisaged duration of data analysis in the CAD (duration of opening of a secure area reserved for the project)** | | | | |
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|  | **8. Information of the thematic RD health networks (FSMR, “Filières de Santé Maladies Rares), rare cancer networks or learned societies** [MAX. 1/2 PAGE]  In the interests of transparency, project leaders are asked to inform the Rare Disease Health Sectors, the national rare cancer networks certified by INCa or the learned societies with the preindications concerned by the project.  *- List of informed FMSRs, networks, or learned societies*  *- Information procedures*  *- Where applicable, collaboration procedures* |  |
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| **BIBLIOGRAPHY** |
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| **APPENDICES** |