October 2024
EMA/716437/2022

# Records of data processing activity for the clinical study data proof-of-concept pilot[1]

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| 1. | Last update of this record, version number | version no. 2, [14 October 2024] |
| 2. | Reference number | TDA-06 |
| 3. | Name and contact details of controller | European Medicines Agency<br>Internally: Head of Data Analytics and Methods Task Force<br>Contact: datacontroller.analytics@ema.europa.eu |
| 4. | Name and contact details of DPO | dataprotection@ema.europa.eu |
| 5. | Name and contact details of joint controllers (where applicable) | The European Medicines Agency (EMA) and National Competent Authorities (NCAs) in Union Member States jointly determine the purposes and means of processing personal data for the Proof-of-Concept (PoC) pilot. Therefore, they are deemed "joint controllers" in accordance with Article 28 of the Union Data Protection Regulation (EUDPR)[2] and Article 26 of the General Data Protection Regulation (GDPR)[3].<br>Which NCAs will act as joint controllers will depend on the regulatory procedures included in the PoC pilot and is not yet known at the time of starting the pilot. A list of the NCAs participating in the pilot as well as their contact details will be provided upon request. |
| 6. | Name and contact details of processor (where applicable) | EMA will engage the following third parties for certain data processing activities:<br>• Data Analytics Centre at Lægemiddelstyrelsen (Danish Medicines Agency) |

[1] Formerly referred to as raw data proof-of-concept pilot
[2] Regulation (EU) 2018/1725 of the European Parliament and the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC.
[3] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation).

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| | | Axel Heides Gade 1, 2300 Copenhagen S, Denmark<br>for the analysis of the clinical study data (contract awarded via procurement procedure under EMA/2020/46/TDA framework contract[4]);<br>• Microsoft Ireland Operations Limited<br>South County Business Park, One Microsoft Place, Carmanhall and Leopardstown,<br>Dublin, D18 P521, Ireland<br>for the storage, access, authorisation and versioning of the clinical study data (SharePoint); and<br>• Microsoft Ireland Operations Limited<br>South County Business Park, One Microsoft Place, Carmanhall and Leopardstown,<br>Dublin, D18 P521, Ireland<br>for the access to and storage of the clinical study data (Azure Virtual Desktop Infrastructure system). |
| 7. | Purpose of the processing | The purpose of the data processing activities is to assess whether the analysis of patient-level data from clinical studies by regulatory authorities improves the evaluation of initial Marketing Authorisation Applications (iMAAs) for new medicines as well as post-authorisation applications and to explore the practical aspects of the submission and analysis of such data in the context of performing EMA's tasks. |
| 8. | Description of data subjects and personal data categories | 'Persons whose data EMA processes' are all data subjects whose data are included within the clinical study data files to be submitted by applicants / marketing authorisation holders in relation to the PoC pilot.<br>Personal data processed may include, but are not limited to, the following (sensitive) personal data:<br>• Investigator name<br>• Data Subject ID<br>• Site<br>• Region<br>• Country<br>• Age of the data subject<br>• Sex of the data subject<br>• Height of the data subject<br>• Weight of the data subject<br>• Trial Treatment group (Experimental / Placebo)<br>• Race of the data subject<br>• Information on follow-up and treatment compliance |

[4] Services - 575628-2021 - TED Tenders Electronic Daily (europa.eu)

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| | | • Health related data variables collected at baseline and all subsequent study visits<br>Such personal data are pseudonymised (which means that they cannot be linked to a specific natural person without the use of additional information which is, however, not processed by EMA). |
| 9. | Retention period | The retention period for the clinical study data files will be the same as for the other core master files from the underlying centralised procedure[5]. |
| 10. | Recipients of the personal data | The clinical study data files received for a specific regulatory procedure will be accessed by:<br>• EMA staff involved in the receipt, storage, management and analysis of the clinical study data;<br>• NCA staff involved in the storage, management and analysis of the clinical study data;<br>• EMA contractors (processors) involved in the processing of the clinical study data. |
| 11. | Are there any transfers of personal data to third countries or international organisations? If so, to which ones and with which safeguards? | Personal data will not be transferred to any third countries or international organisations. |
| 12. | General description of security measures, where possible. | The EMA has put in place appropriate technical and organisational measures (security policies and procedures) to ensure the security of processing in accordance with article 33 of EUDPR. The EMA takes necessary measures to ensure the maximum safety and security of personal data held. The following technical and organisational measures are in place:<br>• EMA has adopted an Internal Guidance on Personal Data Protection, which implements the EUDPR, sets up data protection governance, roles and responsibilities, and specific procedures related to the security of personal data.<br>• Access to the clinical study data files is only granted on a "need-to know" basis.<br>• Data processing agreements are in place with data processors (contractors or software providers).<br>• The clinical study data files will be processed in electronic systems with restricted access and secured by standard EMA security practices in line with EMA's Security policy 0076.<br>• EMA conducts regular testing and reviews of the existing measures to ensure they remain effective and |

[5] SOP_EMA_1004.pdf (eudra.org)

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| | | acts on the results of those tests where they highlight areas for improvement.<br>• A clear and comprehensive procedure for handling personal data breaches exists.<br>• EMA implements measures that adhere to an approved code of conduct which is aligned with ISO 27001 requirements.<br>• The Document Classification Policy 0081 is adopted by EMA to define the classification scheme which supports EMA in identifying documents criticality level and the appropriate security measures to be applied.<br>• Security features of IT solutions used include signing, encryption and Transport Layer Security (TLS)/Secure Sockets Layer (SSL) authentication.<br>• An 'Administrative Arrangement' is in place between EMA and the NCAs which specifies their data governance rules as joint controllers. |
| 13. | For more information, including how to exercise your rights to access, rectification, object and data portability (where applicable), see the data protection notice | Details concerning the processing of your personal data are available on the Agency's website at:<br>https://www.ema.europa.eu/en/about-us/data-protection-privacy<br>Here you may find the data protection notice regarding this specific data processing operation as well. |