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| uw bericht van | uw kenmerk | ons kenmerk | Leuven |
|---|---|---|---|
| 01-04-2022 | | 1833222N | 14-04-2022 |

**ONDERWERP: FWO Mandaat (1833222N) Data management plan**

Datypes that will be collected during the research

- Chemical compound characterization (LC-MS, NMR data; software specific). Quantitative tissue/ cell binding & biodistribution data (gamma counting; csv format & autoradiography; TIFF)
- Radiopharmaceutical synthesis (production logs; paper & PDF).
- Human data
- Trial documents (paper, PDF)
- Demographic & clinical data (source: electronic patient records UZ Leuven (KWS) – data capture through eCRF; Castor).
- Human imaging (PET, CT, MRI; listmode RAW & DICOM format; UZ Leuven PACS & MIM software).
- Image analysis (VOIs; MIM software).
- Ex-vivo analysis (µCT, software specific; histology data, TIFF & software specific; other data, digital lab book)

Provisions are in place in order to preserve the data during and at least 5 years after the end of the research.

Chemical data: data on automatically backed-up (ABU) KU Leuven servers in protected folders (responsible person (RP): F. Cleeren).
Radiopharmaceutical synthesis: data stored according to GMP production license (paper & ABU UZ Leuven servers) (RP: K. Serdons).
Human imaging: data stored according to MiRACLE procedures on ABU UZ Leuven servers (MIM) or in UZ Leuven PACS (BU guarantee: 20 years) (RP: W. Deckers).
Trial documents: paper storage according to GCP (RP: K. Porters)

Clinical data: eCRF in Castor (RP: C. Deroose).
Ex-vivo imaging: data stored on MoSAIC servers (KU Leuven; ABU) according to MoSAIC data management plan (responsible person (RP): C. Cawthorne).

## Specific security measures for sensitive data.

This project will deal with human healthy volunteers and oncological patients. The research will be carried out according to Good Clinical Practice (GCP) norms. All data will either be stored in the protected electronic health care records (EHR) of UZ Leuven (KWS) or will be pseudonymized to be collected in the eCRF for further analysis. The identity of the patients (pseudonymization key) will be stored in the paper Subject Identification Code List, together with the signed Consent Forms, which are kept on site in a locked cabinet (RP: K. Porters). Data will be managed in compliance with the UZ Leuven General Data Protection Regulation (GDPR) policy.

Sufficient storage capacity is provided on the KU Leuven, MoSAIC , PACS and UZ Leuven data drives. Furthermore, sufficient storage is foreseen for advanced data analyses. Data storage costs will be charged to the project.