

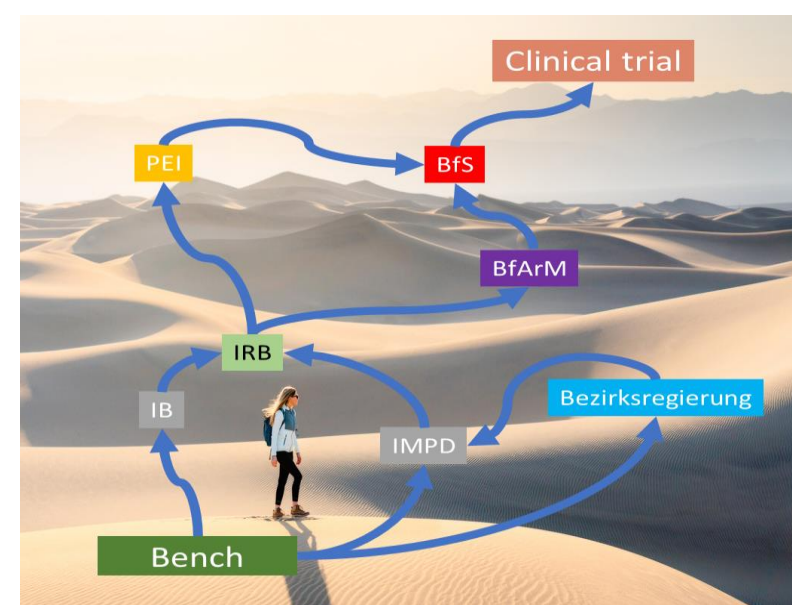
Lighthouse Project – Theranostics

The concept of theranostics is to integrate imaging and therapy for precision medicine of cancer. Bavarian researchers and startup companies are internationally leaders of this field. The lighthouse project aims to foster research in theranostics and to make theranostic innovations available for all Bavarian citizens.

Speaker: Prof. Dr. W. Weber, Munich

Activities & Achievements

Where we started. The two major strategic goals of the lighthouse group are (i) to establish an IMPD (investigational medicinal product dossier) office to foster translational cancer research, and (ii) to improve the clinical availability of radiopharmaceuticals for PET imaging in Bavaria.



The goal of the IMPD office is to streamline the complex regulatory process for clinical translation by a central multidisciplinary team which writes the required documents and interacts with the regulatory authorities (BfArM, BfS and PEI).

The second goal is to improve infrastructure for the GMP production of radiopharmaceuticals in Würzburg and Munich and to supply these to academic and non-academic centers in Bavaria.

Activities and what we achieved.

- After filling the positions of the new IMPD office with experienced staff, an IMPD/IB for the chemokine receptor CXCR4 ligand ⁶⁸Ga-PentixaFor has been written and is available for all BZKF researchers.
- BfArM approval of a prospective clinical trial of CXCR4 targeted imaging and therapy (COLPRIT study) was received in June 2023.
- Phenotypic characterization of tumors in the molecular tumor board of TUM for theranostic approaches has been established.

- Production of ⁶⁸Ga-FAPI-46 is currently established together with the preparation of an IMPD to enable clinical trials.
- BZKF IITs in preparation that are supported by the IMPD office include:
 - Phase I study of **Olaparib** combined with PRRT in SCLC (supported by ITM, Garching)
 - Phase I study of the **αvβ6 integrin** ligand developed at TUM in HNSCC (clinical trial supported by DKH and TRIMT, Dresden)
- An extensive evaluation of radiation dosimetry packages has been completed and a lead candidate for

standardized radiation dosimetry identified.

To make radiopharmaceuticals more available in Bavaria the lighthouse group has:

- Intensified the collaboration of the two hospitals in Munich (LMU & TUM) in radiopharmaceutical production and initiated the tech transfer for ¹⁸F-SITATE production
- Started to make ¹⁸F-PSMA produced in Munich available for patients in Augsburg
- Made ¹⁸F-PSMA produced in Würzburg available for patients in Bayreuth and Bamberg
- Obtained a **production license** for ⁶⁸Ga-PentixaFor in Munich and Würzburg for the COLPRIT study as well as for industry sponsored (PentixaPharm) studies in Augsburg, Munich and Würzburg.

Future goals at all BZKF sites

- » Integration of theranostic approaches in the molecular tumor boards of the BZKF (“phenotypic tumor characterization”)
- » Support of clinical studies on combination of PRRT and external beam radiotherapy and prostate cancer imaging with PSMA ligands
- » Production license and IMPD/IB documents for an FAP ligand to enable BZKF studies
- » Infrastructure for and standardization of radiation dosimetry for clinical studies

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