

Lighthouse project – Imaging and Theranostics

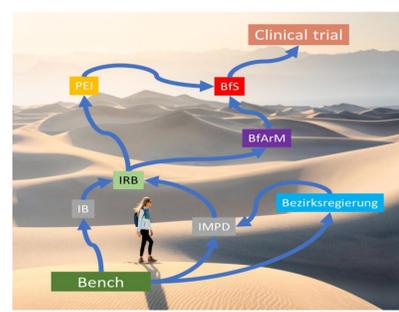
The concept of theranostics is to integrate imaging and therapy for precision medicine of cancer. Bavarian researchers and startup companies are internationally leaders of this field. The lighthouse project aims to foster research in imaging and theranostics and to make theranostic innovations available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

Speaker: Prof. Dr. W. Weber, Munich

Concept & 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.



What we have achieved.

Translational research:

- The positions of the IMPD office have been filled with experienced staff.
- An IMPD/IB for the chemokine receptor ligand CXCR4 has been written and is available for all BZKF researchers.
- This IMPD has enabled the submission of the DKH COPRIT study protocol for IRB review.



- The IMPD office is currently supporting the BZKF study HOMIE of a new medical device by interventional radiology (funded by Quirem).
- 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 an $\alpha\beta6$ integrin Ligand developed at TUM in HNSCC (supported by TRIMT, Dresden)

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

- Made ^{18}F -PSMA produced in Würzburg available for patients in Bayreuth and Bamberg
- Established the supply of ^{18}F -fluoride for radiochemical syntheses in Erlangen
- Obtained a production license for ^{68}Ga -Pentixafor in Munich and Würzburg for the COLPRIT study as well as for an industry sponsored (Pentixapharm) study in mantle cell lymphoma in Augsburg, Munich and Würzburg.

Future Milestones

- » 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

Authors: Prof. W. Weber (München), Prof. A. Buck (Würzburg), Prof. C. Lapa (Augsburg), Prof. M. Uder (Erlangen)