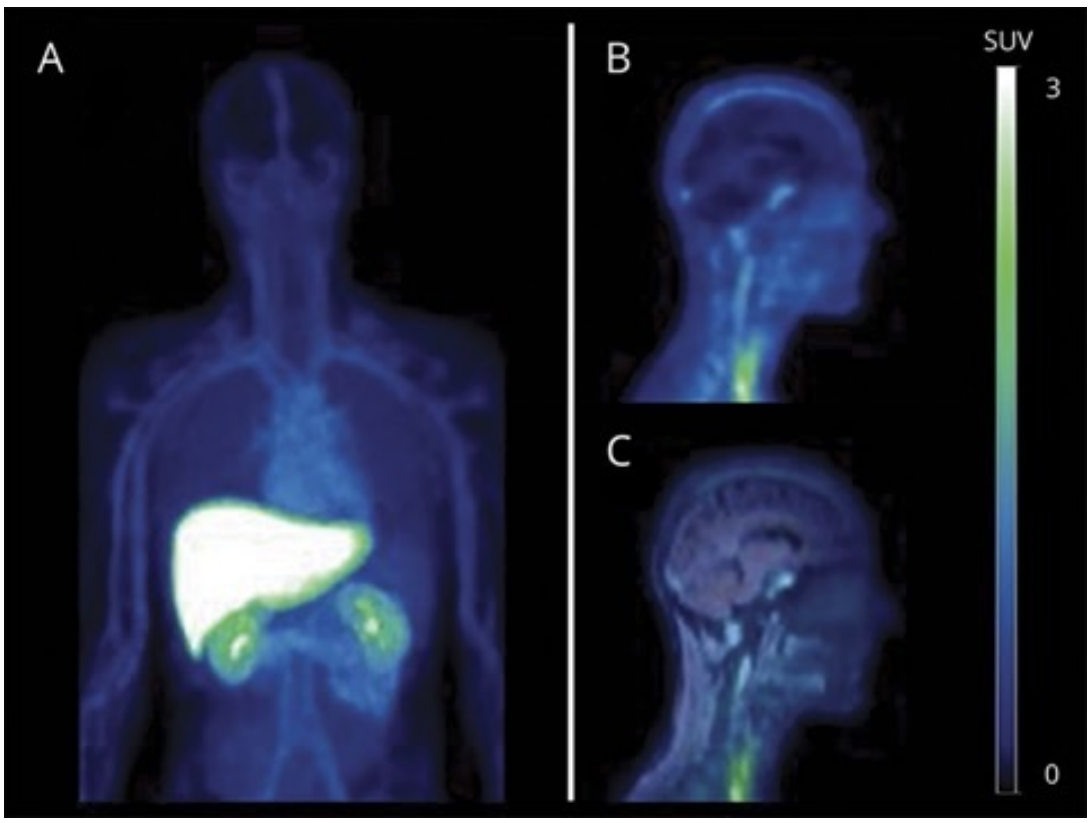
PET Microdosing
PHASE-0 imaging trial

In a few years, PET imaging has emerged as an essential diagnostic approach, especially for the detection of tumors. This same technology is now revolutionizing medical research, in a new drug development paradigm called microdosing / phase 0 imaging trial.

The approach, which consists in testing microdoses of drug candidates in humans, makes it possible to test the efficacy of a molecule upstream of the development of a drug.



Biodistribution study showing negligible penetration of a radio-labelled drug in brain.
Summed PET projection (A), brain PET (B), and PET-MRI fusion (C) images obtained in a 30-year-old man after injection of ^{11}C-glyburide (Marie *et al.* 2019)

Key Features

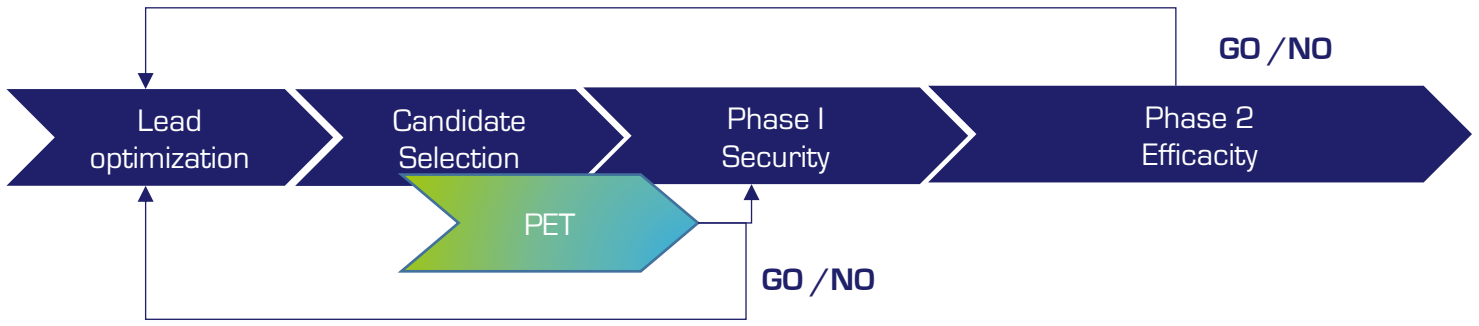
- Microdose (no toxicity, no side-effects)
- Tests in volunteers and patients
- First in man

Evaluation of drug candidates

- Biodistribution
- Target engagement
- Mechanism of action
- Drug-drug interaction

Safer, Accelerated, Targeted, and Human-Specific Translation in Drug Development

PET imaging enables efficient decision making long before traditional clinical validation phases



Estimated benefits of a 350 k$ on 4-12 patients in a 6 to 8 months study

12 Months Gain on drug development roadmap

1.5 M$ Saved for each stopped inefficient candidate

300 M$ Value of backup compound re-prioritization after failure of a non-viable lead candidate

CHANGED PARADIGM

- Get new analytics tools for biologics drugs
- Avoid translation failure from animal models to human

BETTER PRODUCTIVITY

- Gain early data on pharmacokinetic, pharmacodynamic, target engagement and mechanism of action
- Save GMP time

IMPROVED SECURITY

- Decrease pharmacological risk with subtherapeutic dose exposure
- Reduced regulatory files according to FDA's eIND guidelines

ANTICIPATED REGULATORY CHANGES

- Compliant with ICH M3 guidelines for clinical trials
- Reduced use of animals in human drug development

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PASREL-Project

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