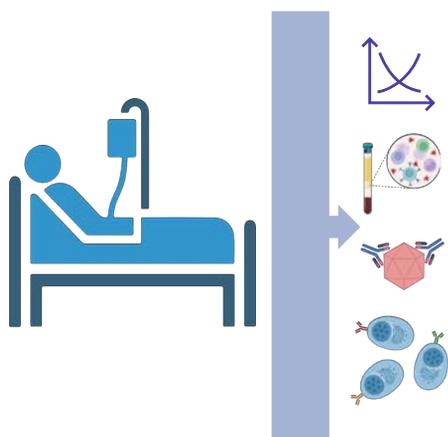


BIOANALYTICAL METHODS



Key questions

- How is the drug being absorbed, distributed and excreted from the body?
- Will the drug trigger any immunogenic response that may impact the efficacy and safety of the drug?
- Does the drug affect any biomarker level? Is this clinically meaningful?



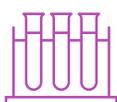
Testing of blood and other bodily fluids

- Pharmacokinetics (distribution, absorption, excretion and half life)
- Pharmacodynamics (disease specific biomarkers)
- Immunogenicity (anti-drug antibody, neutralizing antibody and T-cell responses)

Prerequisites for bioanalytical testing

Reagents

- Drug product
- Antibodies
- Controls for different assays
- Reference standards



Assays

- Fit-for-purpose
- Pharmacokinetic measurements
- Pharmacodynamic readouts
- Immunogenicity testing



Each program requires specific reagents and assays. The process of acquiring reagents and developing the assays should begin early in product development