



# True Dose® Blood Sampling: A Valuable Tool in Modern Drug Development

True Dose® is an innovative sampling and bioanalytical platform designed to simplify and secure drug concentration measurements across clinical research and drug development. The platform enables a unified workflow from patient led blood sampling to certified bioanalysis, providing the dense, high quality exposure data needed to meet modern regulatory expectations.

## The Regulatory Imperative: Why Data Density Matters

The landscape of drug development has shifted toward quantitative dose optimization, with increasing regulatory focus on dose–exposure–response characterization for both efficacy and safety. Initiatives such as the FDA Oncology Center of Excellence Project Optimus emphasize robust dose selection strategies supported by adequate clinical pharmacology evidence. In this context, traditional sparse venous sampling can be insufficient to characterize inter-individual variability and to support model-informed dosing decisions

### Platform Specifications

<b>Sample Type:</b>	Whole Blood
<b>Sample Volume:</b>	Fixed-volume capillary collection (50µL)
<b>Collection Time:</b>	< 5 minutes
<b>Analytes:</b>	Small molecules, metabolites, ADCs (Free vs. Conjugated)
<b>Shipping:</b>	UN3373 compliant packaging via standard post
<b>Sample Stability:</b>	Metabolite dependent, typically 14 days in ambient temp.
<b>Automation:</b>	Compatible with standard 96-well plate holders
<b>Analysis:</b>	Validated LC-MS/MS assays in ISO13485 accredited labs

## The True Dose® Solution: Patient-Centric Sampling

Our technology enables patient-centric home sampling, providing the dense data necessary to model exposure-response relationships and accelerate your clinical development program without overburdening trial sites or patients.

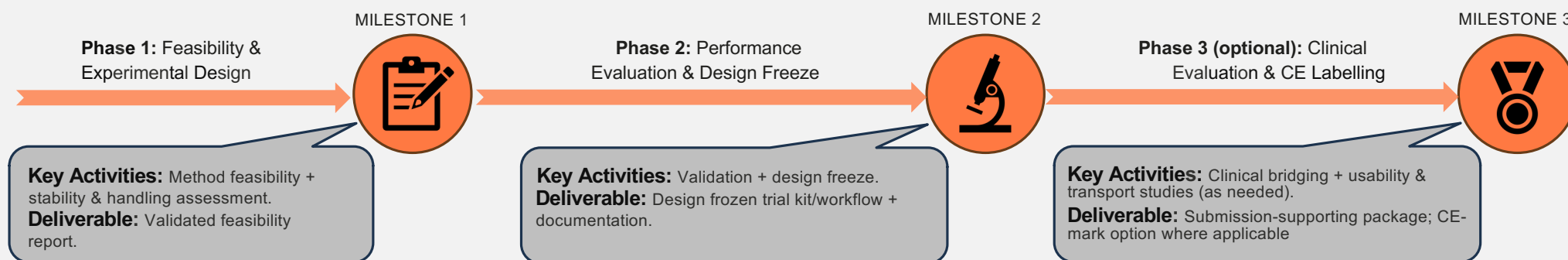
### Key Capabilities:

- **Patient-Led Sampling:** Fixed volume capillary device enables convenient home sampling.
- **Instant Analyte Stabilization:** Patented “Lab in a Tube” technology initiates protein precipitation and suppression of enzymatic activity at the moment of collection, improving integrity for instability-prone drugs and metabolites during transport and handling.
- **Reduced Variability:** An internal standard introduced at collection reduces operator- and handling dependent bias.
- **Global Study Ready:** Ambient-temperature shipment simplifies logistics and supports more consistent pre-analytical handling across multi-center studies (UN3373-compliant shipping).
- **Automation-Ready:** Compatible with standard 96-well robotic workflows for seamless integration and scalability.
- **Advanced Modalities:** Platform designed to be extensible to more complex modalities (e.g., ADC-related workflows), subject to analyte-specific feasibility and validation.



## A Structured, milestone-based program

We adapt the True Dose® workflow to your drug candidate and study design through a structured, milestone-based program. Timelines are typically **8–15 months**, depending on analyte properties and validation requirements. Key activities and outputs are summarized below.



## Technology capabilities: "The Lab in a Tube"

### Generation 1 (Commercial Ready)

**Focus:** Small molecules & metabolites

**Application:** PK profiling from patient led capillary whole blood sampling with in-device stabilization and internal standard at collection to reduce pre-analytical variability.

**Validated Example:** Tamoxifen and Endoxifen

### Generation 2 (planned for Q3 2026)

**Focus:** Extended workflows for complex modalities (as applicable).

**Application:** Simultaneous measurement of **Free vs. Conjugated** drug in a single sample via in-device incubation prior to precipitation.

## Deliverables: Submission ready data

We provide a data package that supports exposure measurement/optimization and regulatory interactions by reducing practical and logistical barriers to include more patients and capture exposure-relevant timepoints across treatment cycles without overburdening trial sites.

- **Certified bioanalysis:** LC–MS/MS assays performed in qualified partner laboratories operating under ISO 13485 quality systems, with validation scope aligned to intended use and study phase.
- **PK parameters (AUC, C<sub>max</sub>, C<sub>trough</sub>):** Decentralized sampling improves feasibility to obtain exposure-relevant samples needed for robust estimation of key PK parameters.
- **Exposure response modelling:** Increased feasibility to include more patients improves dataset completeness and statistical power to quantify exposure efficacy and exposure–toxicity relationships, strengthening benefit/risk decisions and dose optimization.

Partner with us to de-risk your drug development program

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