



PCSIG



Patient Centric Sampling in Pediatric Clinical Trials – Successes, Challenges and How to Overcome Them

Patient Centric Sampling Interest Group Webinar – 1st March 2023

Thank-you to our Partners and Sponsors



Agenda

Neil Spooner - Chair, PCSIG

- Welcome and introduction to patient centric sampling

Enaksha Wickremsinhe – Senior Director, Eli Lilly & Co.

- Small patients, big challenges

Jeff Silverman – Senior Research Fellow, Edgewise Therapeutics

- Exploring the use of home blood sampling in pediatric Duchenne muscular dystrophy

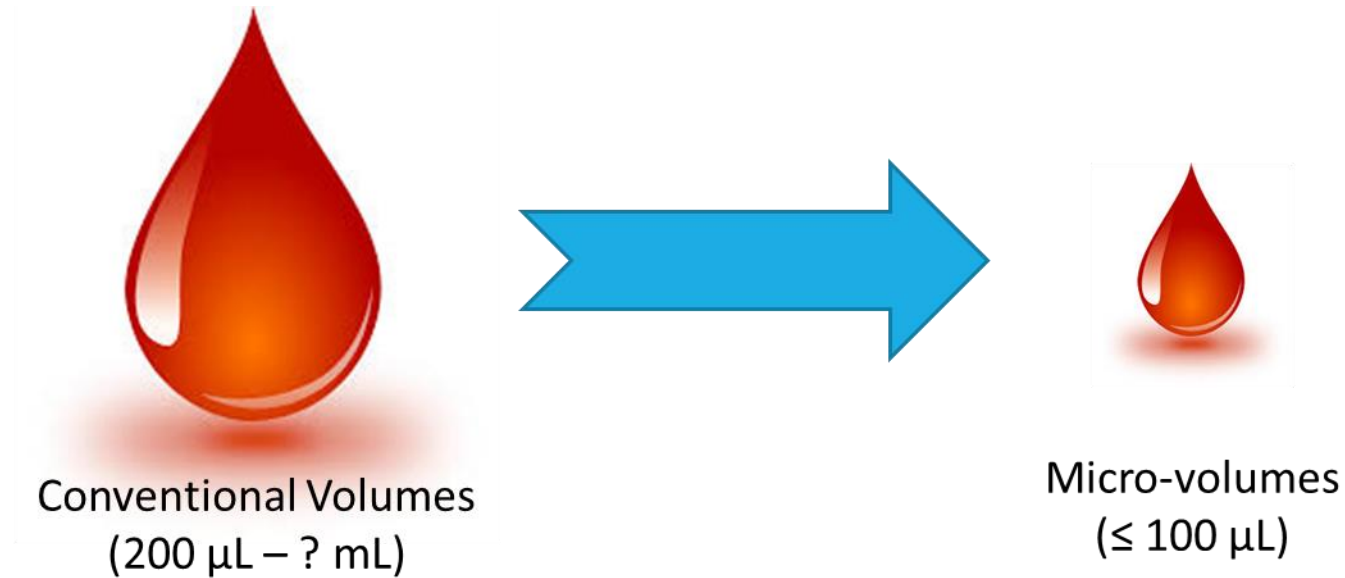
Panel Discussion

- Please enter your questions throughout the webinar

Neil Spooner – Chair, PCSIG

- Wrap-up

What is Patient Centric Sampling?



It is **NOT** simply about collecting smaller blood volumes



.....it **IS** about moving beyond conventional blood sampling and putting the patient at the center of the process

It is about collecting.....

...the appropriate sample...

...using a process that is most convenient for the patient...

...that provides high quality information...

...to make high quality decisions

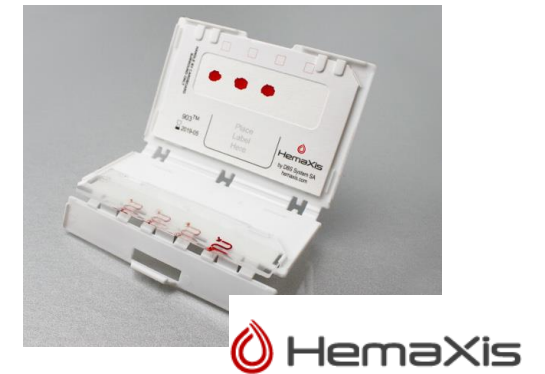
This may be blood sample volumes of 10 μL ,
or it may be 400 μL



A number of novel approaches are now commercially available



Including.....



Benefits of Patient Centric Blood Sampling



Quality

Obtaining a high quality blood / plasma / serum sample for accurate quantitative determination of drugs, drug metabolites & endogenous molecules

Patient

Minimising the impact on the human patient / consumer

- Optimising blood volume sampled
- Minimising pain and invasiveness
- Facilitating convenience

Enriched Data

Generating high quality concentration data in situations that are currently difficult, or impossible to work with

Where might PCS be of benefit?

Reduce patient burden, particularly for vulnerable populations, e.g.

- Pediatrics, elderly, oncology, anemia
- Rural locations
- Etc....

Additional data for PK and biomarkers

- Improved PopPK modelling
- Improved understanding of disease

Data during a clinical event, e.g.

- Migraine, asthma, AE's, etc

Potential for improvement in clinical trial patient recruitment & retention

- Shorten clinical trial timelines
- Improve diversity

Understanding patient compliance

