Using Remote Sampling in Clionical Trials – Overcoming the Hurdles to Implementation

Neil Spooner

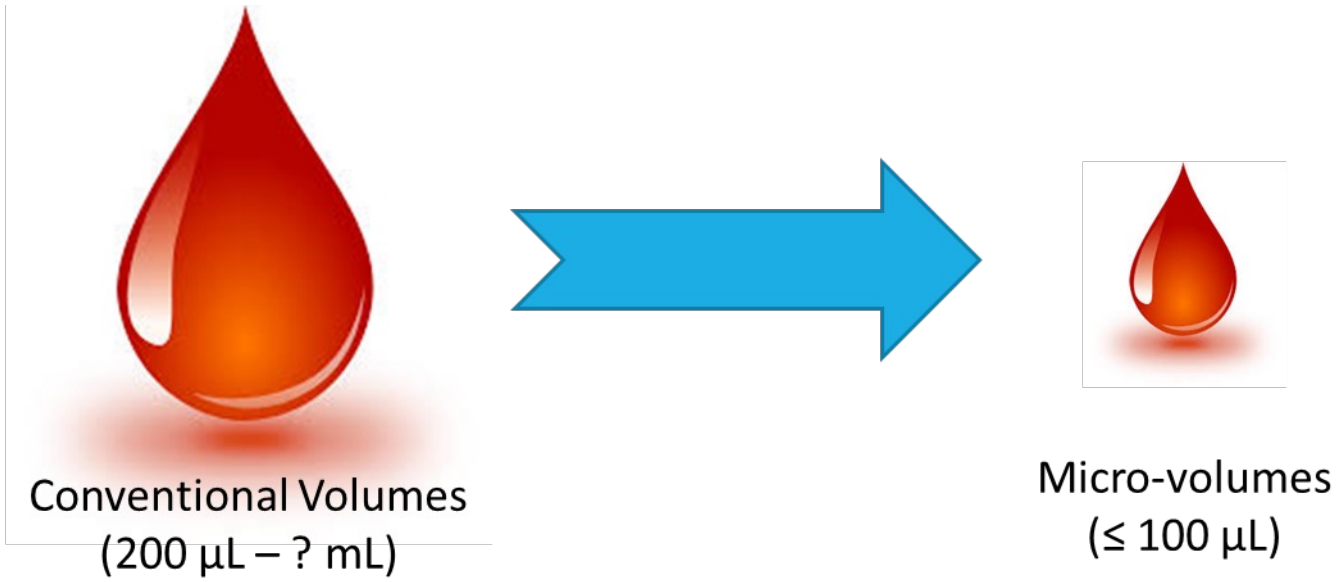
Founder - Patient Centric Sampling Interest Group

Founder – SPOONER BIOANALYTICAL SOLUTIONS

Senior Visiting Research Fellow - University of Hertfordshire UH

(neil@spoonerbioanalytical.co.uk)

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 250 µL

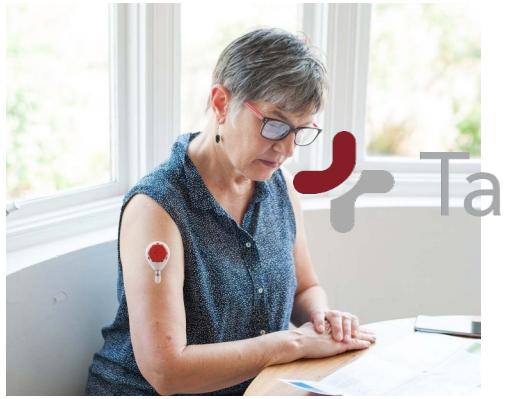
A number of novel approaches are now commercially available

PCSIG

Including…..

neoteryx®
The promise of microsampling, delivered

TRAJAN



Tasso

Winnoz

Capitainer

yourbio

RHINOSTICS

loop
medical

HemaXis

Benefits of Patient Centric Blood Sampling

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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

But it’s not all plain sailing……

What are the Challenges? Bioanalytical

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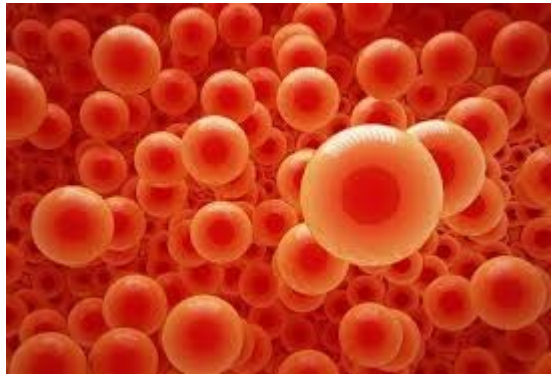
Additional method development & validation requirements



- Effect of blood hematocrit on analyte recovery
- Stability
  - Has to mirror conditions experienced by the samples during transit and storage
  - Increased temperature, low temperature, humidity
- Presence of anticoagulant
- How to perform sample dilutions
- Lot-to-lot variability of sample collection device
- Different devices for different study designs

Bioanalytical lab workflows & automation

Creation of calibrants & QC samples

Supported by preferred CROs

What are the Challenges? Pharmacokinetic

The samples obtained from these technologies could be

- Whole blood vs plasma vs serum
- Wet vs dry
- Capillary vs venous

The concentrations of an analyte of interest may be different

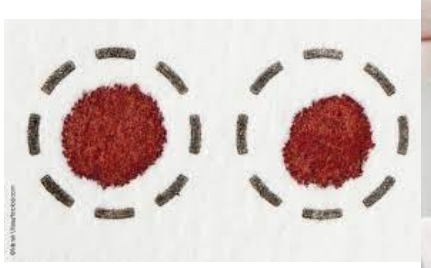
- Comparison to exiting non-clinical and clinical data

Requirement to assess in vitro blood / plasma

Requirement to perform clinical bridging studies

Obtaining accurate times for dosing & sampling

May require complex modelling



What are the Challenges? Logistics & Operations

Potential compromise of patient confidentiality

Confirmation of patient identity

Supplies & logistics

Labelling

Expiry dates

Storage prior to use

Sample integrity & chain of custody

Device regulatory approval & availability in different countries

Consistency of supply throughout clinical programme

Training – staff, patients, caregivers

- Languages

Engage early in the planning process

What are the Challenges? Regulatory

Regulatory status of the PCS device

- Country differences

Acceptability of bioanalytical data

Patient reported data

- Sampling time

Engage with ethics and regulators early

How can we Overcome the Challenges?

Within our organisations

Between organisations

- EBF
  - Open Symposium
    - Plenary
    - Workshops
  - Surveys
- AAPS
  - Conference sessions
  - Webinars
  - Surveys
- PCSIG

Patient Centric Sampling Interest Group

A not-for-profit organization that brings together a variety of interested parties who wish to develop & promote the use of patient centric blood sampling technologies for the advancement of human healthcare & well-being

Clinical trial

- Understand whether home vs in-clinic blood sampling has an impact on clinical trial recruitment & retention

Diagnostics Working Group

- Publications
  - Economic use cases
  - Summary of guidelines for bridging diagnostic test with PCS
- Buyers guide

Surveys

- Clinician
- Patient

Education

- Engaging key stakeholders at international conferences
- PCSIG webinars

Contact us

- https://www.pcsig.org/
- contact@pcsig.org

Conclusions

PCS brings a number of benefits

Increasing interest and acceptance

Challenges

- Beyond the bioanalytical lab

Overcome challenges & make progress by working together

- Passion
- Persistence

Thank-you

neil@spoonerbioanalytical.co.uk

Some useful reading

KF Maass et al (2022) Leveraging patient-centric sampling for clinical drug development and decentralized clinical trials: Promise to reality. *Clin. Transl. Sci.* doi: 10.1111/cts.13411.

ER Wickremsinhe et al (2020) Land O'Lakes workshop on microsampling: enabling broader adoption. *AAPS J.* doi:10.1208/s12248-020-00524-2.

K Bateman (2020) The development of patient-centric sampling as an enabling technology for clinical trials. *Bioanalysis.* doi:10.4155/bio-2020-0075.

C Bailey C (2020) Giving patients choices: AstraZeneca's evolving approach to patient-centric sampling. *Bioanalysis.* doi:10.4155/bio-2020-0105.

S Capiau et al (2019) Official International Association for Therapeutic Drug Monitoring and Clinical Toxicology Guideline: Development and Validation of Dried Blood Spot–Based Methods for Therapeutic Drug Monitoring. *Ther. Drug Monit*. doi: 10.1097/FTD.0000000000000643

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