

A 3D puzzle with one red piece standing out. The puzzle pieces are dark grey and arranged in a grid. One piece in the center is red and is slightly raised from the others, which are flat. The background is a dark grey gradient.

An Update from the Community on Microsampling and Patient Centric Sampling – Turning Imagination into Reality

— Neil Spooner —

Patient centric sampling means moving beyond this.....

....for the collection of high quality blood samples for quantitative analysis



To technologies that put the needs of the patient / animal at the centre



But making the change can be difficult!



It depends on how you look at it!

A number of organisations are working across boundaries to get “stuff” done





AAPS BioAnalytical Community Microsampling Scientific Team

courtesy of Enaksha Wickremsinhe (Eli Lilly and Company)

Initiated (in 2016) to continue cross-industry discussions, following the sun-setting of the IQ Microsampling Working Group

Current group consists of 17 active members (representing Pharma, CROs, Academia, & independent consultants)

Accomplishments:

- AAPS webinar on Microsampling (highlighting advancements in technology & clinical applications) - 2018
- Survey on microsampling (involving IQ, EBF, & AAPS membership) - 2018
- Engagement with blood sampling tube manufacturers in quest for smaller volume standard blood collection tubes - ongoing
 - Discussions with vendors on vacutainers that can collect <500 µL blood
- Regulatory engagement – invited to present to the FDA BioA Scientific Interest Group - April 2019
- Workshop on Microsampling: Land-O-Lakes conference – 2020

AAPS / EBF Survey & Publication

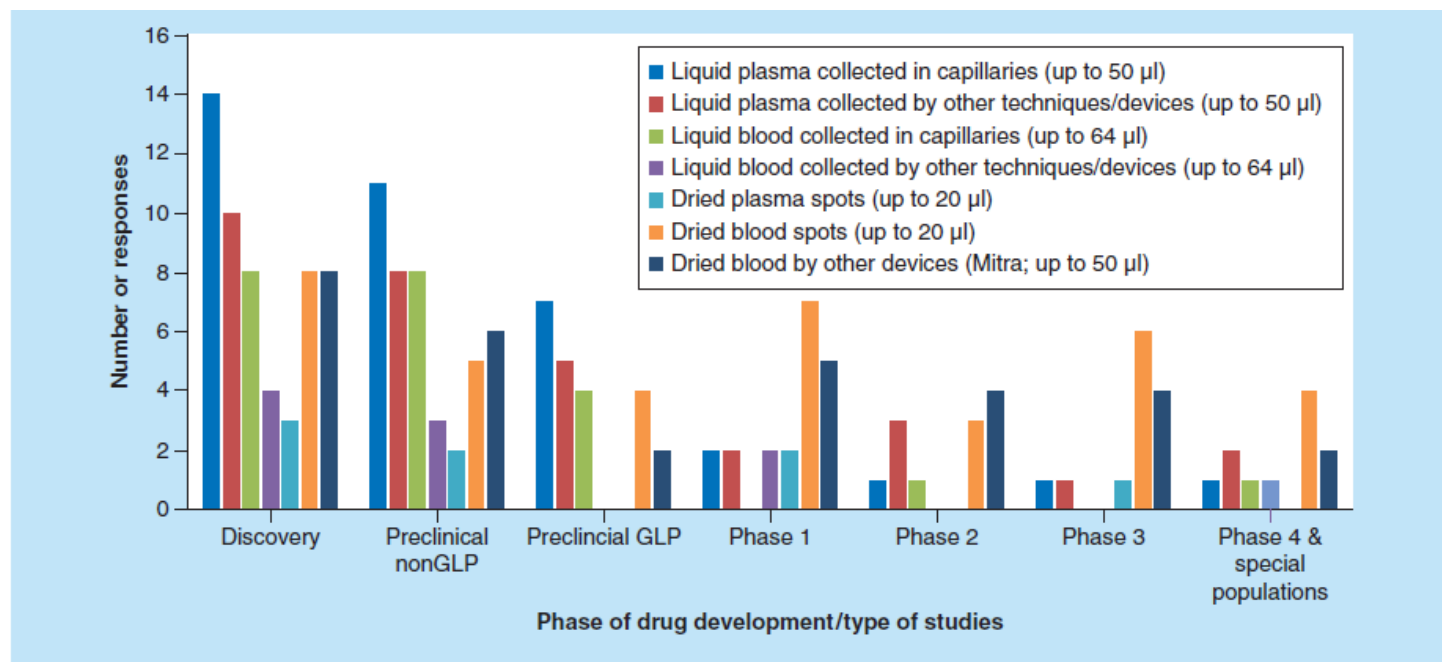


Figure 1. Utilization of different microsampling approaches for studies at various stages of drug development. The data represents responses from 39 different pharmaceutical companies and contract research organizations.

Patel *et al.* (2019) Microsampling for quantitative bioanalysis, an industry update: output from an AAPS/EBF survey. *Bioanalysis* **11**(07) 619-628



INTERNATIONAL CONSORTIUM *for*
INNOVATION & QUALITY
in PHARMACEUTICAL DEVELOPMENT

Patient Centric Sampling

IQ Discussion Group
(Courtesy of Melanie Anderson, MSD)

ACKNOWLEDGEMENT

This presentation was developed with the support of the International Consortium for Innovation and Quality in Pharmaceutical Development (IQ, www.iqconsortium.org). IQ is a not-for-profit organization of pharmaceutical and biotechnology companies with a mission of advancing science and technology to augment the capability of member companies to develop transformational solutions that benefit patients, regulators and the broader research and development community.

Patient Centric Sampling Discussion Group (PCS DG)

Background: A previous IQ working group discussed emerging technologies for use in drug development¹. The PCS DG was formed to provide a forum for discourse around alternative sampling technology and patient centric sampling.

Problem statement: Emerging Technologies present unique opportunities to enhance data sets in clinical trials, improve enrollment opportunities, and make clinical trials more patient centric. Patient-centric sampling, such as in-home sampling with less painful and intrusive methods, is one critical component to success in this area. Despite the potential benefits, the application of in-home sampling is limited across the pharmaceutical industry. There is a lack of understanding on the current status and a need for more mature sampling technologies. Best practices are undefined, and the global regulatory environment is unclear. Combining efforts to advance this novel approach in the pre-competitive space is a great need.

Membership: Translational and ADME Leadership Group (TALG) and
Clinical Pharmacology Leadership Group (CPLG)
22 members from 17 different pharmaceutical companies

¹Kothare, P. A., et al (2018), Harnessing the Potential of Emerging Digital Health and Biological Sampling Technologies for Clinical Drug Development: Promise to Reality. *Clin. Pharmacol. Ther.*, **104**: 1125-1135.

Patient Centric Sampling Discussion Group

Mission: The purpose of the IQ PCS DG is to fill potential knowledge gaps in the field, and provide a forum for cross-industry practitioners to share and define best practices on in-home sampling to provide richer data sets for drug development. Understanding and shaping the regulatory landscape for in-home sampling will also be critical for success.

Discussion Points:

- Value proposition for in-home sampling
- Current state of in-home sampling
- Gaps and challenges for in-home sampling
- Devices and micro-sampling techniques
- Best Practices for analytical method validation
- Data analysis requirements
- Optimal processes for clinical operations
- Acceptance within the industry & with regulators
- Regulatory landscape for in-home sampling

Goal: The DG first met in April 2019 and meets monthly for discussion. The DG will provide a recommendation to the TALG and CPLG by the end of 2019 on whether the group should transition into a Working Group. Specific deliverables will be provided for a working group.



PCSIG

Patient Centric Sampling Interest Group

- Founded at CPSA USA 2017
 - Thank-you Mike Lee
- Free to join
- >90 members
- >50 different organisations
 - CROs, biotech, pharma, hospital labs, central labs, clinical operations, device innovators, instrument vendors, consumable vendors, consultancies, publishers, *etc*
- Collaborate across organisations in non-competitive areas of mutual interest
- Workplace platform – Facebook product
 - Sharing of documents
 - Conversations
 - Thank-you Trajan Scientific and Medical
- Want to join?
 - Write to - neil@spoonerbioanalytical.co.uk



Current Activities – Standardisation

- Building an industry standard
 - CLSI
 - IVD Industry Connectivity Consortium
 - Fast Healthcare Interoperability Resources - FHIR
- “Standardization of metadata associated with the use of patient centric blood sampling devices for the quantitative determination of circulating analyte concentrations”
- Activities led by:
 - Søren Therkelsen, Neil Spooner, Greg Nagy, Tim Richards, Enaksha Wickremsinhe, Pawanbir Singh, Cory Zuehlendorf, Florian Lapierre



Current Activities – Acceptance

- Facilitating the broad acceptance of patient centric sampling technologies and pathways to their implementation
 - Public, Scientific community, Medical community, Legislators, Payers, Regulators, Media, etc.....
 - Building external facing website
 - Thank-you Future Science
- Activities led by:
 - Florian Lapierre, Jinming Xing, Tim Richards, Neil Spooner, Kayte Parlevliet



Current Activities – Convincing Stakeholders

- What does PCS do that I can't do now? What does it enable? Beyond
 - Rare diseases
 - Remote access
 - Pediatrics
 - Access to vulnerable patients
- Will PCS save money / time in my trials?
 - Can PCS accelerate recruitment efforts?
 - Can PCS reduce dropout rates?
 - Can PCS increase engagement and adherence?
 - How can we demonstrate these values?
- What is the added risk of PCS?
 - Is there an added regulatory / analytical risk?
 - What can we do to further reduce that risk?
- Activities led by:
 - Erwin Berthier, Neil Spooner



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← **Designing Clinical Trial**



National Centre
for the Replacement
Refinement & Reduction
of Animals in Research

NC3Rs

Focussed on the 3Rs in animal use

- Replace, Reduce, Refine

UK Government funded, with industrial co-funding for specific programmes

- Work and input becoming increasingly international

International User Group

- 27 companies and regulators
- Perform surveys
- Lead workshops
- Publish outcomes
- Website focussed on microsampling practicalities
 - <https://www.nc3rs.org.uk/microsampling>

Renewed activity in 2019

- Steering group met in October 2019
- Expanding beyond Pharma
 - Academia
 - Agrochem
 - etc....
- Expanding links to other international 3Rs organisations
- Review of website
- Surveys – where are the gaps?
- Leading to future activities
- Thank-you Helen Prior
 - Let us know if you want to get involved (Helen.Prior@nc3rs.org.uk)

European Bioanalysis Forum

EBF has been actively engaged in highlighting microsampling approaches since 2008

- Regular presentations and sessions on the topic have been made at the Open Forum
- Organised Focus Meetings & Workshops (2010, 2011, 2012, 2013)
- Surveys performed and reported (2009, 2018)
- Cross company experimental activities and discussions to better understand the technologies
 - DBS-microsampling consortium (2011)
 - HCT effect, homogeneity
 - Liquid microsampling consortium (2013)
 - Volumetric accuracy, homogeneity
- Wide variety of publications (11) arising from the above
- The future - as of 2019
 - Patient centric / home sampling team
 - Preclinical studies (3Rs) team



Patient centricity is at the heart of all CPSA events

- Home to the PCSIG
- Thank-you Mike Lee

Inclusivity of all stakeholders

- CROs, biotech, pharma, clinical operations, hospital labs, central labs, clinicians, device innovators, instrument vendors, consumable vendors, consultancies, investors, publishers, **CLINICIANS, PATIENTS**

Focus on the **HOW?** and **WHEN?**, rather than the WHAT? and WHY?

Learning from other areas of expertise

Conversations move around the world and around the calendar

Give space for discussion and reach consensus

- Openly shared and published

Education

- Short courses

Inclusive of the next generation

- Our legacy

Conclusions

Interest in Patient Centric Sampling is ongoing and growing

Benefits to organisations can be realised

Change is difficult

Working together across boundaries eases the pain

- And is more fun! 😊

If you are interested in getting more involved in any of these activities and groups, then please let me know



THANK YOU
