



# Introducing Patient Centric Sampling: What it is and How it Could Transform Clinical Diagnostics?

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# Biography and Contact Info



- Senior consultant at BioData Solutions LLC
- Twenty+ years of combined experience in LBA, ADA, cell-based assays, nAb, and data science in discovery and regulated bioanalysis
- Joleen earned her PhD degree in biochemistry from The Scripps Research Institute and BS in chemistry from Harvey Mudd College

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## Conflict of Interest:

Prior employee of Gates Medical Research Institute, a grantee of the Gates Foundation who also issues grants to device developers and manufacturers

# What is Patient Centric Sampling?

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Moving beyond conventional blood sampling and putting the patient at the center of the process



# It is about collecting.....

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...the appropriate sample...

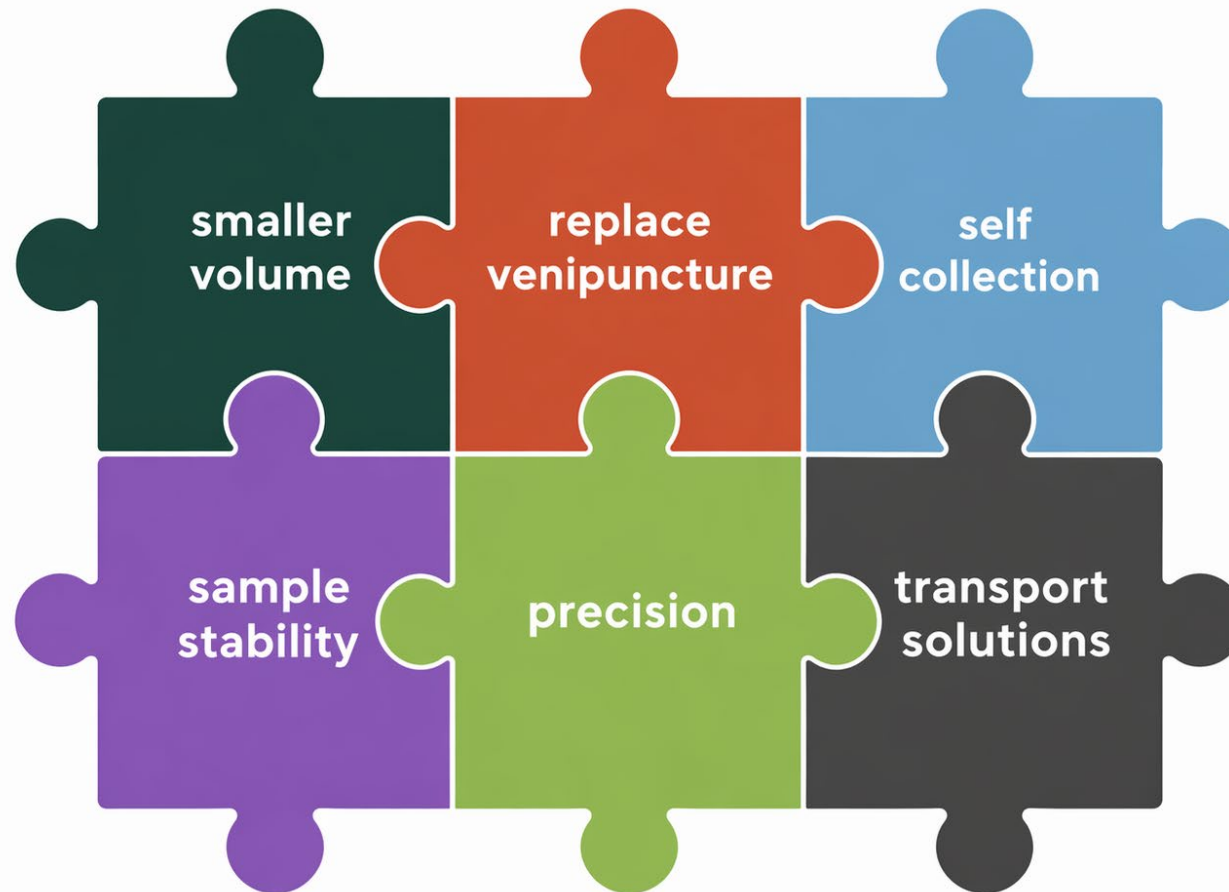
...using a process that is most convenient for the patient...

...that provides high quality information...

...to make high quality decisions



# Technology solutions



# A number of novel approaches are now commercially available



Including.....



Comprehensive lists can be found at <https://www.pcsig.org/> under Technologies

# No One-Size-Fits-All

Technologies developed to solve a particular problem

Not all challenges share the same solution

- DBS great for heel prick newborn screening for Pos/Neg readout
- DBS terrible for complete blood count (CBC)

Alternate approaches solve different problems

No one approach solves all problems

- Example: Cost burden for more complicated devices

**Question for ASLM to consider for 7-May discussion:**

- Who are the patients that are currently underserved?
- Does PCS open up new opportunities for solutions?
- What existing technology solve African challenges?
- Which African challenges need new solutions?



# What limits innovation in US vs Africa

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The status quo is easier to maintain despite disadvantage to patient

Barriers to innovation (in US)

- Heavy capital investment of laboratories for vacutainer automation
- Financial benefits to better diagnostic access not same payer as potential increase in test cost
- Adapting 510(k) assays to use alternate sample puts burden on each individual lab

**Question for ASLM to consider for 7-May discussion:**

- What are the barriers to innovation in Africa?
- Which cross-country efforts could be leveraged (e.g. African Medicines Agency)?
- How could you build diagnostic access differently with patients in the center?
- Who are the stakeholders in diagnostic access and reimbursement?
- What are regional nuances to challenges?



# Potential applications

## Shared Principle – Access for all patients in all locations

### Infectious disease:

- Pathogen identification
- Serological surveillance
- HIV viral load

### Diagnosis

- Risk factors (including genetic)
- Diagnostic tree
- Disease progression
- Establishing normal ranges

### Treatment monitoring

- Therapeutic drug monitoring
- Side effect tracking
- Therapeutic targets
- Support clinical trials

### Testing in support of telehealth visits

# Where do we go to next?



# Patient Centric Sampling Interest Group

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*"Enabling patients to take control of sampling"*

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

**Visit our Website**



**Contact us**

[contact@pcsig.org](mailto:contact@pcsig.org)

**Join our LinkedIn Group**



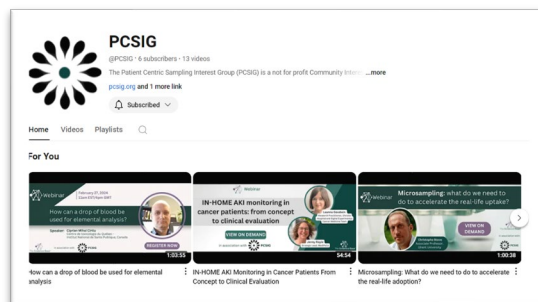
# PCSIG Activities

Free Webinars: <https://www.pcsig.org/webinars>

Sampler technology listings: <https://www.pcsig.org/bloodsamplers>

PCS Library (including webinars, publications, etc): <https://www.pcsig.org/library>

Resources to support PCS for clinical trials: <https://www.pcsig.org/clinicaltrials>



PCSIG  
 (PCSIG) 4 subscribers · 13 videos  
 The Patient Centric Sampling Interest Group (PCSIG) is a not for profit Community Interest Group (CIG) for patients, clinicians, researchers, industry and 1 more link  
 PCSIG.org and 1 more link  
 Home Videos Playlists

For You

- How can a drop of blood be used for elemental analysis?
- IN-HOME A&I Monitoring in Cancer Patients From Concept to Clinical Evaluation
- Microsampling: what do we need to accelerate the real-life adoption?

### Patient Centric Blood Samplers

The information on this page was sourced from the Vendors listed website, or publicly available information. It has been confirmed by the Vendors unless indicated by \*. As such, the PCSIG bears no responsibility for the accuracy of the content. This table is for guidance only and is not intended to make any recommendations regarding the technologies and vendors featured. Given the complexities of global device regulation, the regulatory status is not provided. Please contact the device vendors to determine whether the regulatory status of a particular technology is suitable for your application.

The content of the table is reviewed several times per year and is correct as of 13th September 2023. Please message [contact@pcsig.org](mailto:contact@pcsig.org) if you have any amendments to this table.

Please note that viewing of this table works better on desktop devices.

Vendor	Brand Names	Matrix	Volume	Precise Volume Collection	Sampling Type	Available for Purchase	Website
Ahlstrom	BioSampleTRN	dried blood	70 µL	N	lancet finger stick	Y	<a href="http://www.ahlstrom.com/sciences-and-technologies-and-its">www.ahlstrom.com/sciences-and-technologies-and-its</a>
Ahlstrom	Gensaver 2.0	dried blood	125 µL	N	lancet finger stick	Y	<a href="http://www.ahlstrom.com/sciences-and-technologies-and-its">www.ahlstrom.com/sciences-and-technologies-and-its</a>
Ahlstrom	HemaSep	dried plasma (punch/strip)	100/80 µL	N	lancet finger stick	Y	<a href="http://www.ahlstrom.com/sciences-and-technologies-and-its">www.ahlstrom.com/sciences-and-technologies-and-its</a>
BD	BD MinDraw™ Capillary	liquid blood	225 x 635 µL	N	lancet finger	Y	<a href="https://www.bd.com/usa/en/products/point-of-care/point-of-care-testing/point-of-care-testing-devices/point-of-care-testing-devices-devices/point-of-care-testing-devices-devices-devices">https://www.bd.com/usa/en/products/point-of-care/point-of-care-testing/point-of-care-testing-devices/point-of-care-testing-devices-devices/point-of-care-testing-devices-devices-devices</a>

### Patient Centric Sampling Resources

Explore our patient centric sampling resources to get an insight into how this approach is being successfully deployed for a number of fields and applications. This content is selected from the PCSIG website and from the websites of other organisations.

PCSIG takes no responsibilities for the accuracy of the content provided from external websites.

If you have any suggestions of content that you think would be useful to add to this page, then please write to [contact@pcsig.org](mailto:contact@pcsig.org)

Pharmaceutical Development

Sport

Sampling Technologies

Economic Use Cases

Public Health

Patient Populations

Analytical Considerations

Regulation & Governance

Physician Led Healthcare


**Patient Perspectives**

Training

Logistics


#### Patient Perspectives

External Article




Self-Sampling by Adolescents at Home: Acceptability and validity of use

PCSIG Webinar




Acceptability and validity of use

External Article



Diagnostic testing preferences can be used to inform the design of patient centric sampling devices

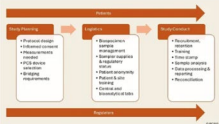
External Article



Patient Centric Healthcare - what's next?

### PCS for Clinical Trials

This page contains a number of resources for those wishing to use PCS in clinical trials. The content is intended for guidance only. If you have any recommendations for the content on this page please let us know at [contact@pcsig.org](mailto:contact@pcsig.org)




#### Proceedings from PCSIG Workshop - Incorporating Patient Centric Sampling into Multicentre Clinical Trials

This document describes the output from the workshop held at Roche's facilities in Welwyn Garden City, UK on 11 and 12 June 2024 attended by 48 individuals representing pharmaceutical and biotech companies, contract research organisations, technology and solutions vendors, academia, publishing and consultants.

The report content includes discussion around a number of challenges encountered when incorporating PCS into clinical trials and suggestions on how to overcome these and potential future activities.

#### Check-list: Integrating Patient Perspectives into Clinical Trials

This document outlines a number of considerations to ensure that the voice of the patient is central when designing and performing clinical trials. It is an essential part of designing and running clinical trials and adapting to rising patient needs.

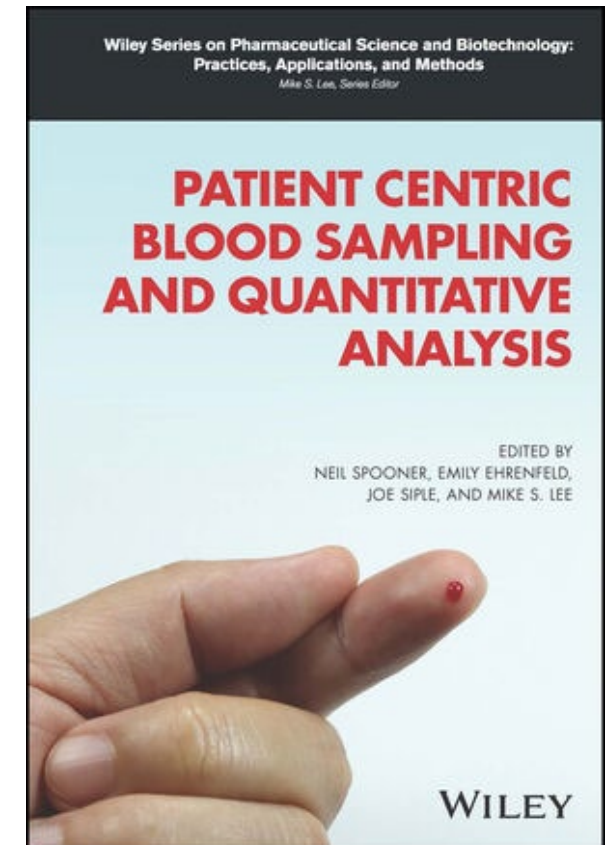




# Book – Patient Centric Blood Sampling and Quantitative Analysis



1. Patient Centric Healthcare – What’s Stopping Us? - J Royle & R Jones
2. Tips for Successful Quantitative Assay Development Using Mitra Blood Sampling with Volumetric Absorptive Microsampling – J Rudge
3. Preanalytical Considerations for Implementation of Microsampling Solutions - BB Collier, et al
4. Collection and Bioanalysis of Quantitative Microsamples: Technological Innovations and Practical Implications - RV Oliveira, et al
5. Automation in Microsampling: At Your Fingertips? - S Deprez, et al
6. Over 50 Years of Population-Based Dried Blood Spot Sampling of Newborns; Assuring Quality Testing and Lessons Learned – AM Gaviglio, et al
7. Considerations for Implementation of Microsampling in Pediatric Clinical Research and Patient Care - GS Moorthy, et al
8. Simplification of Home Urine Sampling for Measurement of 2,8-Dihydroxyadenine in Patients with Adenine Phosphoribosyltransferase Deficiency - UA Thorsteinsdottir, et al
9. Utilization of Patient Centric Sampling in Clinical Blood Sample Collection and Protein Biomarker Analysis - J Xing, et al
10. Enabling Patient Centric Sampling Through Partnership: A Case Study – C Bailey, et al
11. Perspectives on Adopting Patient Centric Sampling for Pediatric Trials - E Wickremsinhe



# Some useful reading

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N Spooner, et al (2025) Patient centric blood sampling and analysis for diagnostics and laboratory medicine. *Bioanalysis*, **17**, 1283–1293 <https://doi.org/10.1080/17576180.2025.2572289>

BB Collier, et al (2025) Comparing capillary blood collection technologies: assessing patient experience, device performance, & clinical accuracy. *Bioanalysis*, **17**, 1329–1336 <https://doi.org/10.1080/17576180.2025.2580284>

DCW Poland, CM Cobbaert (2024) Blood self-sampling devices: innovation, interpretation and implementation in total lab automation. *Clin. Chem. Lab. Med.* **63**, 3-13 <https://doi.org/10.1515/cclm-2024-0508>

L Delahaye, et al (2021) Alternative Sampling Devices to Collect Dried Blood Microsamples: State-of-the-Art. *Ther. Drug Monit.* **43**: 310-321. DOI: 10.1097/FTD.0000000000000864

S Capiou 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.* **41**: 409-430. DOI: 10.1097/FTD.0000000000000643

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