

Microsampling to enable home-based drug monitoring

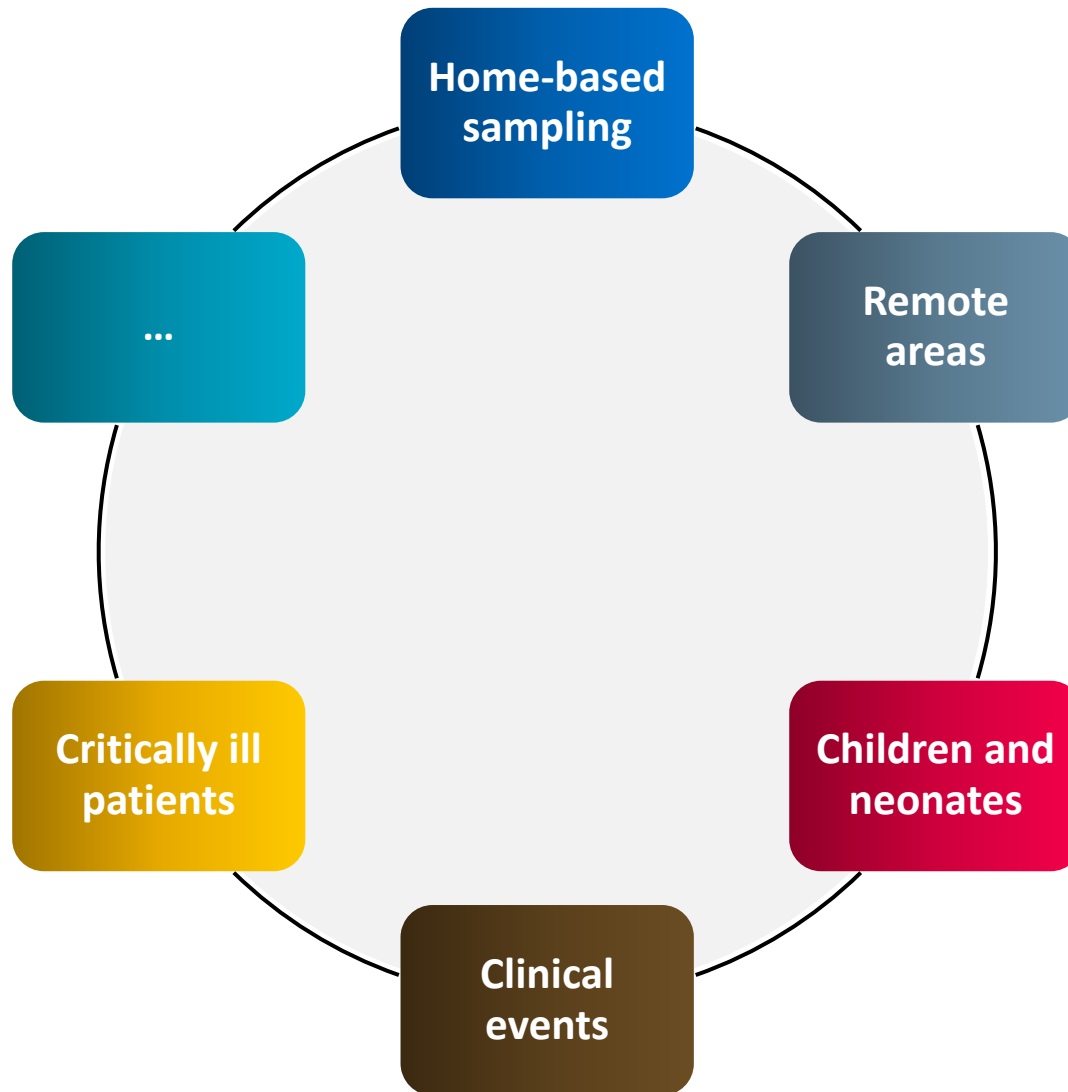


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Microsampling applications in drug monitoring



Microsampling methodology

Finger prick



Microsampling methodology

Finger prick



Non-volumetric sampling



Microsampling methodology

Finger prick



Non-volumetric sampling



Experience

PROS

- Easy
- Low costs

CONS

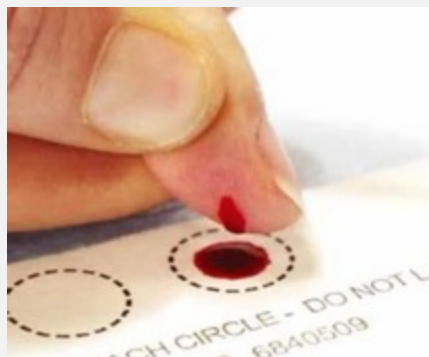
- Haematocrit issues

Microsampling methodology

Finger prick



Non-volumetric sampling



Experience

PROS

- Easy
- Low costs

CONS

- Haematocrit issues



- Area bias
- Recovery bias
- Matrix effect bias

Microsampling methodology*

Finger prick



Volumetric sampling devices



HemaXis DB, by DBS System SA



Mitra®, by Neotyrax



HemaPEN™, by Trajan Scientific



Capitainer-B, by Capitainer

* More devices available

Microsampling methodology*

Finger prick



Volumetric sampling devices



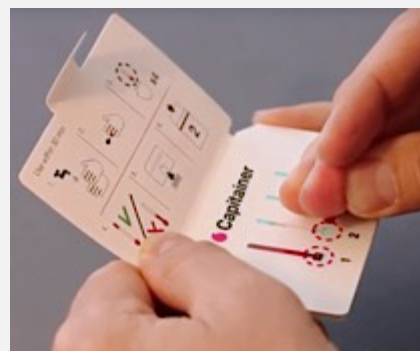
HemaXis DB, by DBS System SA



Mitra®, by Neotytrex



HemaPEN™, by Trajan Scientific



Captainer-B, by Capitainer

Experience

PROS

- Less haematocrit issues

CONS

- More complex
- Higher costs
- Innovation

* More devices available

Microsampling in clinical TDM

DBS-based TDM publications in 2009-2014¹

- ACE inhibitors
- Analgesics
- ATII receptor antagonists
- Antibiotics
- Anticonvulsants
- Antidepressants
- Antimalarials
- Antimycotics
- Antiretrovirals
- Diuretics
- Histamine-H2 receptor antagonists
- Immunosuppressants
- Oncolytics
- Statins
- β -agonists
- β -blockers

1: Wilhelm *et al.* Clin Pharmacokinet 2014.

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Microsampling at LUMC

Conventional venepuncture TDM

Transplant recipient
on tacrolimus
therapy

Venepuncture
sampling at the clinic
(trough, 2h, 3h)

Tacrolimus
quantification
(LC-MS/MS)

Interpret result
and adjust dose
accordingly

Repeat at next
TDM instance



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Dried blood spot TDM²

Transplant recipient
on tacrolimus
therapy

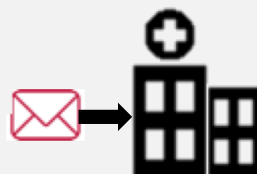
DBS sampling at
home
(trough, 1h, 2h, 3h)

Send DBS
sample to clinic
via regular mail

Tacrolimus
quantification
(LC-MS/MS)

Interpret result
and adjust dose
accordingly

Repeat at next
TDM instance



Challenges at the clinic

Implementation

- Convincing clinicians
- Right device for the right patient



Challenges at the clinic

Implementation

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- Right device for the right patient

Collaboration



Challenges at the clinic

Implementation

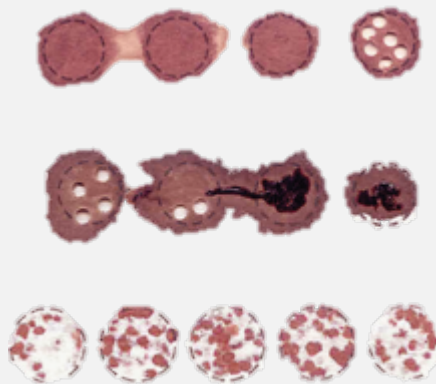
- Convincing clinicians
- Right device for the right patient

Collaboration



Sampling

- Sampling errors
- Handling errors



Challenges at the clinic

Implementation

- Convincing clinicians
- Right device for the right patient

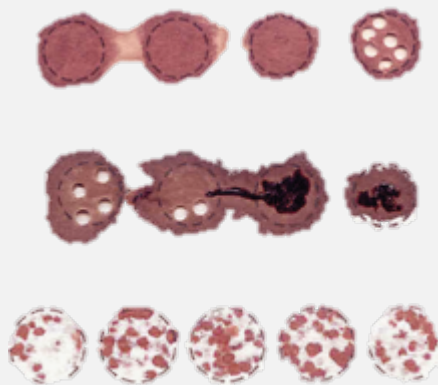
Collaboration



Sampling

- Sampling errors
- Handling errors

Training and guidance



Challenges at the clinic

Implementation

- Convincing clinicians
- Right device for the right patient

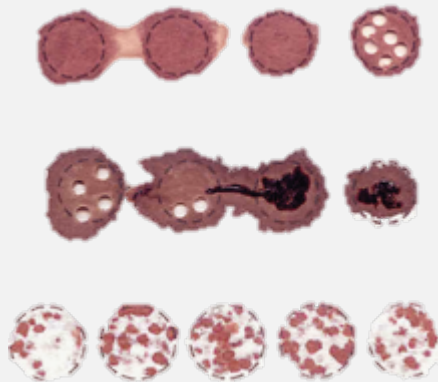
Collaboration



Sampling

- Sampling errors
- Handling errors

Training and guidance



Logistics

- Turn-around time
- Missing samples



Challenges at the clinic

Implementation

- Convincing clinicians
- Right device for the right patient

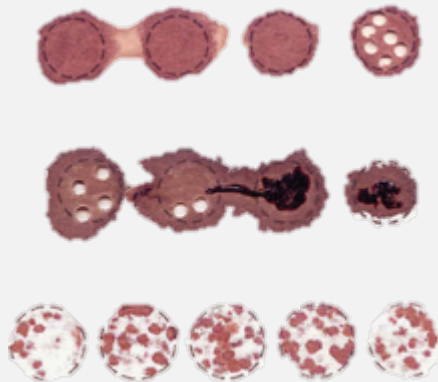
Collaboration



Sampling

- Sampling errors
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Training and guidance



Logistics

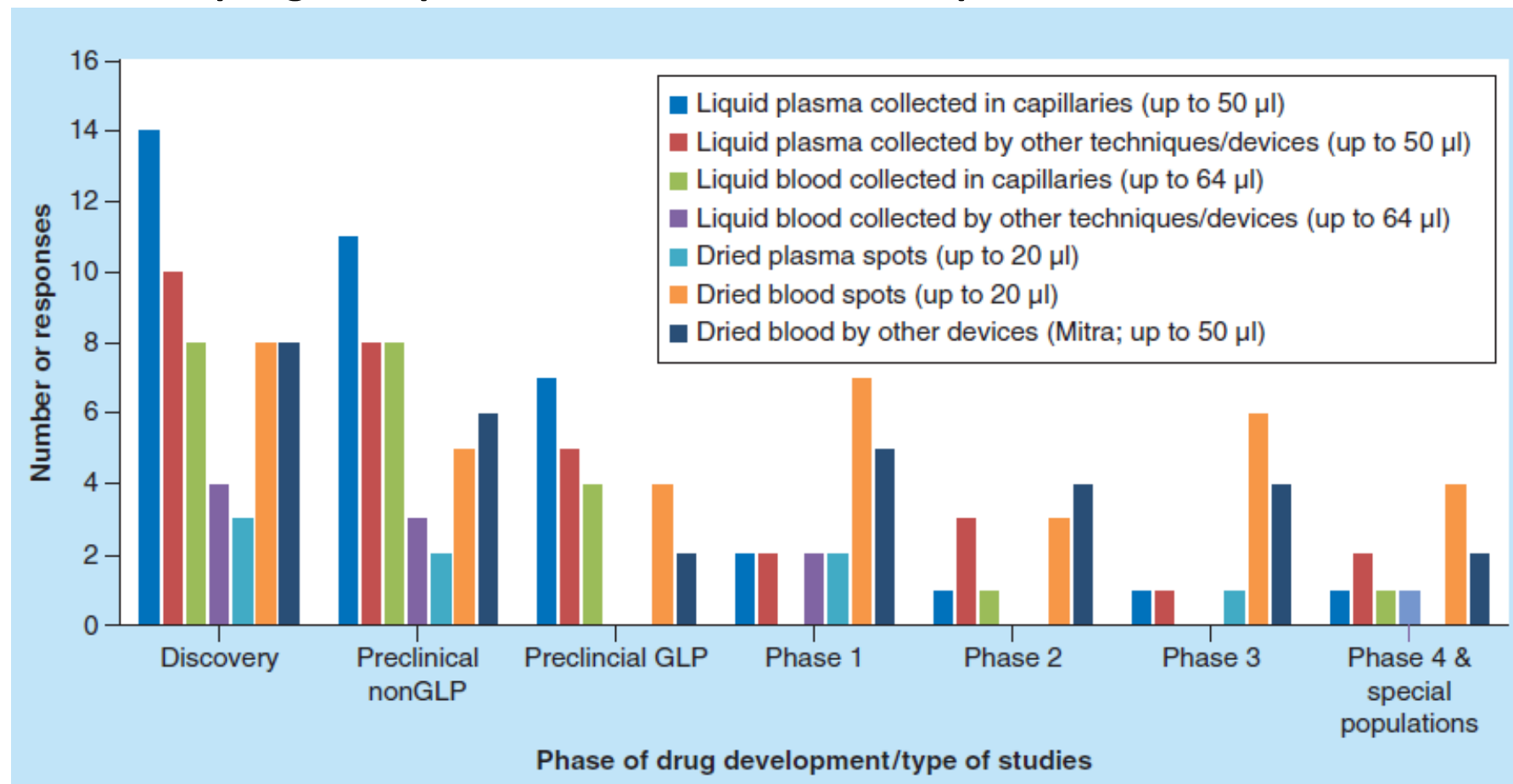
- Turn-around time
- Missing samples

Track and trace



Microsampling in industry

Microsampling in 39 pharma / CRO / biotech companies³



3: Patel *et al.* Bioanalysis 2019.

Microsampling in industry

Drug repertoire

- Small molecule drugs: majority of microsampling approaches
- Biotherapeutics:
 - Trypsin digestion LC-MS/MS detection⁴⁻⁷
 - Infliximab⁸ and adalimumab^{9,10}

4: Kehler *et al.* Bioanalysis 2011.

5: Slecza *et al.* Bioanalysis 2012.

6: Kaendler *et al.* Bioanalysis 2013.

7: Zhang *et al.* Bioanalysis 2016.

8: Berends *et al.* Br J Clin Pharmacol 2019.

9: Kneepkens *et al.* Br J Clin Pharmacol 2017.

10: Berends *et al.* Ther Drug Monit 2019.

Microsampling in industry

Drug repertoire

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Points of consideration

- Feasibility: assay sensitivity, analyte stability, bioanalysis, logistics
- Training and guidance: patients and clinical staff
- Bridging studies: interchangeability with venepuncture sampling¹¹
- Regulatory interaction: microsampling policies and requirements

4: Kehler *et al.* Bioanalysis 2011.

5: Slecza *et al.* Bioanalysis 2012.

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8: Berends *et al.* Br J Clin Pharmacol 2019.

9: Kneepkens *et al.* Br J Clin Pharmacol 2017.

10: Berends *et al.* Ther Drug Monit 2019.

11: Capiou *et al.* Ther Drug Monit 2019.

What's in the pipeline?

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Patient-centric wearable blood sampling devices*



Tasso OnDemand, by Tasso Inc.



TAP100, by Seventh Sense Biosystems



Fluispotter, by Fluisense

* More devices available



Questions?