Fundamentals of Biosensors and Electronic Biochips

Bioassay Development and Validation

- A Medical Device Innovation and Product Development Perspective -

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About myself…

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Now, Biomedical Sciences Director, Liom Health AG (Zurich area)

Non-Executive Director and Advisor, Rea Diagnostic SA (EPFL)

Current Member of two CLSI Working Groups (Allergy assays; Sepsis diagnostics)

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My goals for this lecture are to:

- Get an overview of what it takes to develop and bring to market novel medical devices / IVDs
- Give you a flavour of good practices in medical device / in vitro diagnostics (IVD) development
- Provide you with an overview of the state-of-the-art bioassay development and validation practices
- Give examples of how new technologies can change medical diagnosis

At the end, I would like you to understand that:

- The market and your customers know (usually) better than you what is needed – listen to them!
- Planning is key when developing a product ("Do it right first time" mindset)
- Quality management and Regulatory compliance – if well used – are your allies, not your foes
- A great Bioassay Developer has deep technical skills, and the capacity to look beyond its activities by understanding market access, regulation, manufacturing…

Part I From an idea to a product – feedback from my 15 years in MedTech innovation

Part II Fundamentals in bioassay development and validation

Part III Practical examples of how new technologies are developed to solve medical needs

Q/A, discussion

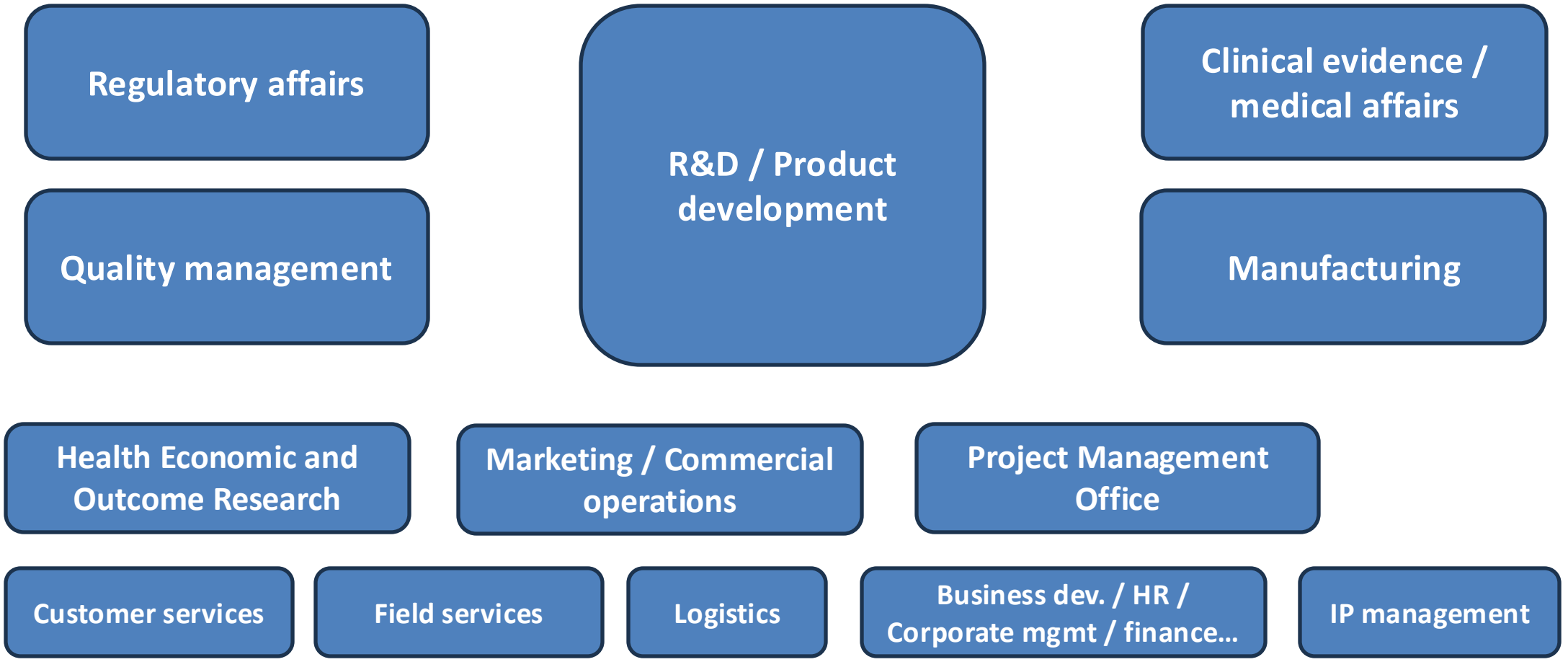
PART I

Innovation in medical device

– From an idea to a concept –

MedTech is a vast field with many opportunities – R&D is just one of them

We will focus today on Product development, touching its links with QA, RA, and clinical evidence



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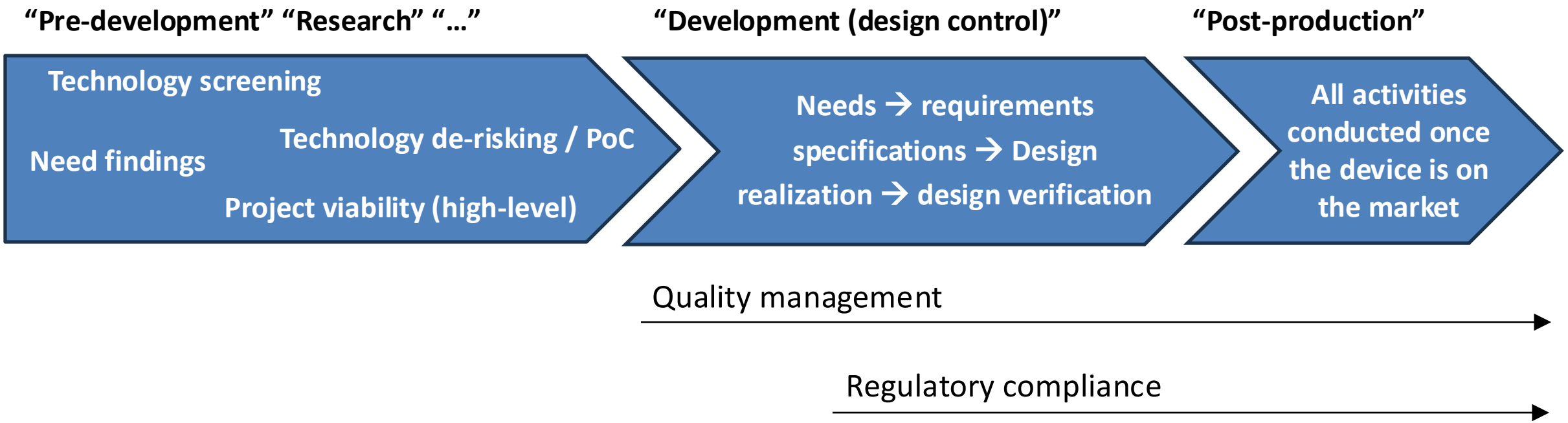
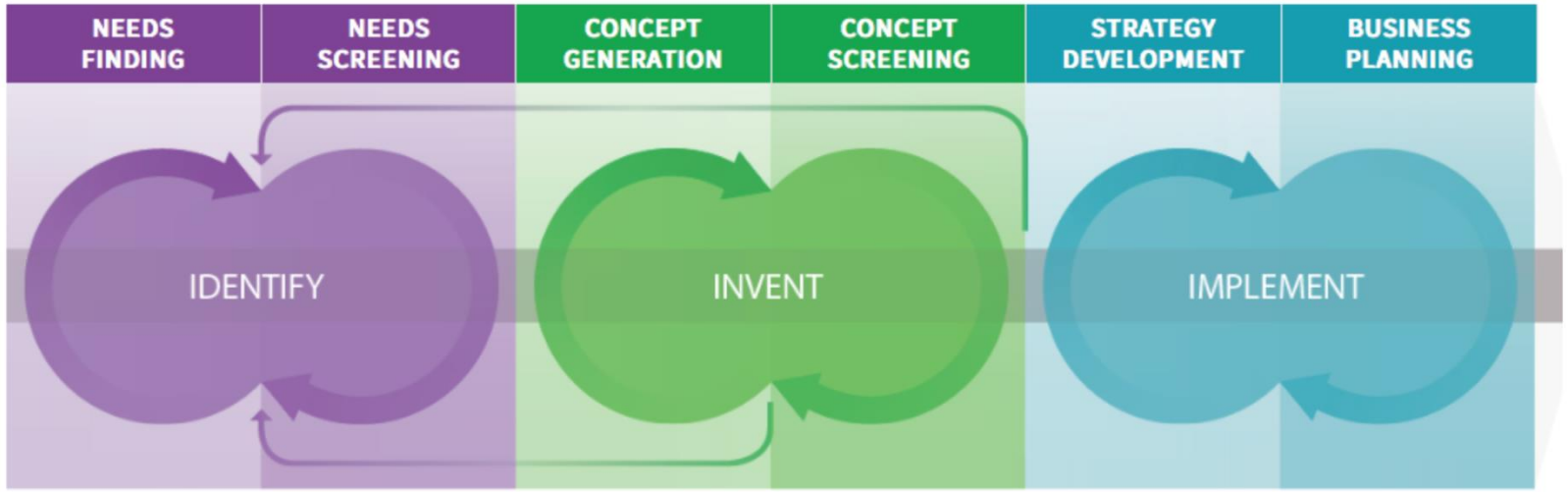
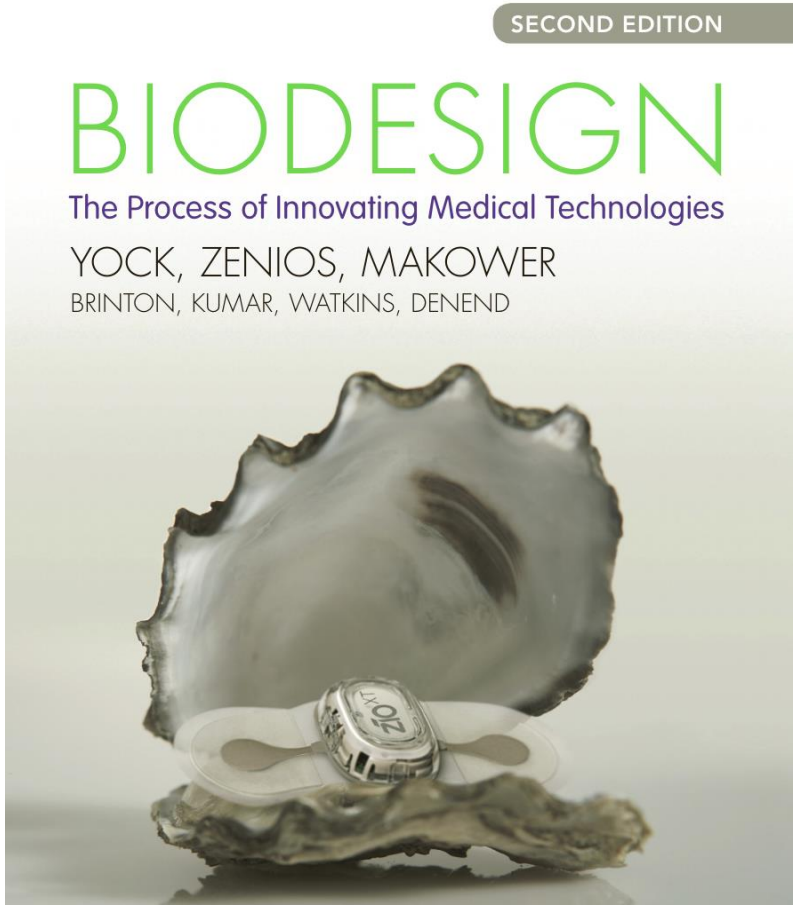


The Biodesign framework aims at helping identifying needs

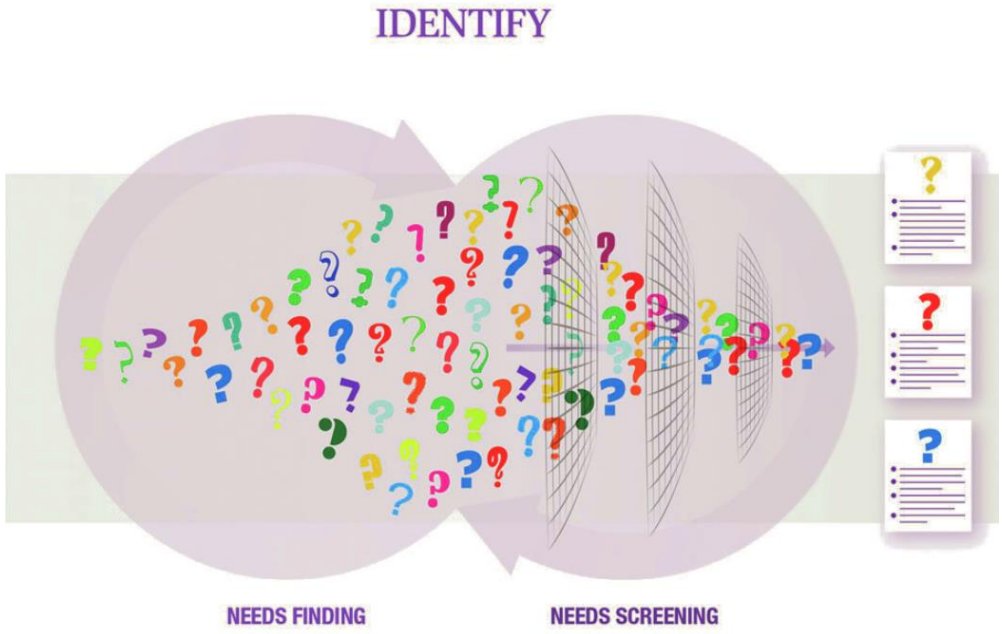
Pre-Development - The Biodesign book is a step-by-step guide to medical technology innovation, with cycles of deliverables and deeper analyses to ensure Agile-style de-risking and progression

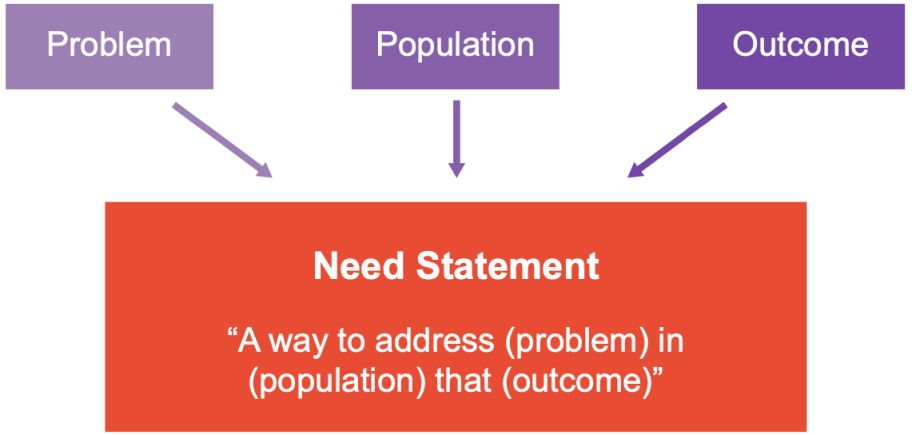




Start by identifying and formulating “needs”

”Identify” consists of gathering unmet medical needs through observation and then reducing this list to a promising few based on information about the key clinical, stakeholder, and market characteristics





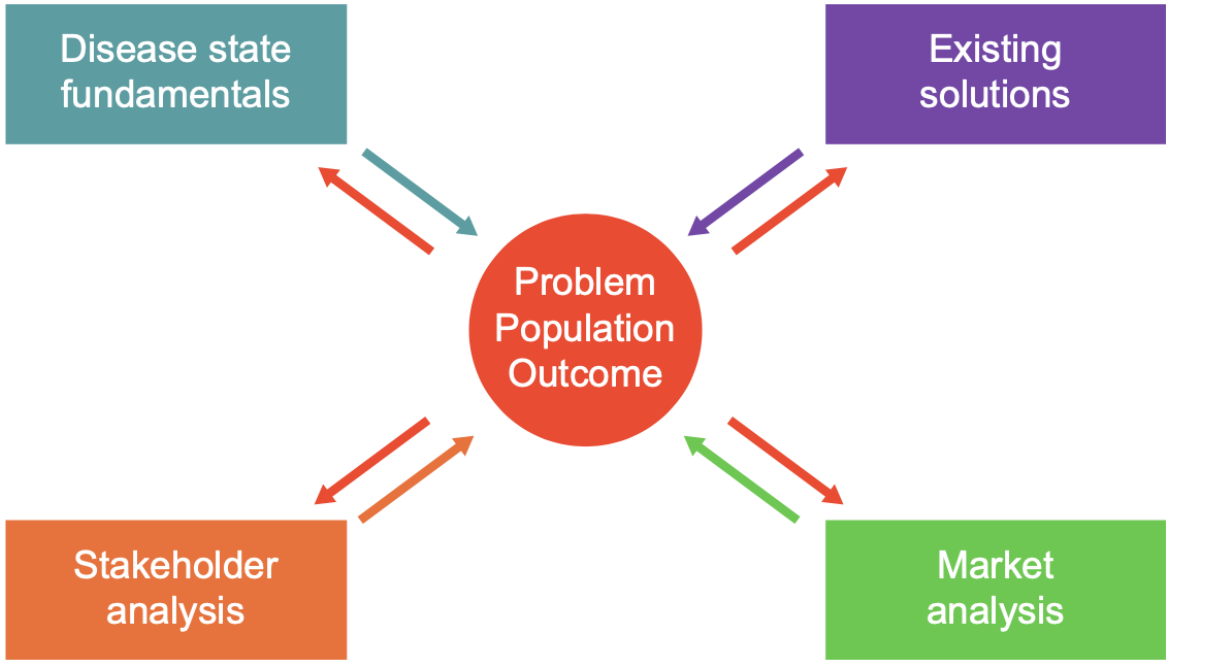
“A way to improve glycemia control in adults leaving with insulin-treated type 2 diabetes mellitus to prevent disease complications associated with lower quality of life, higher mortality, and high healthcare expenditure”

Start by identifying and formulating “needs”

Need screening consists of a quick survey of multiple areas – do not focus on technology only, but also do not lose too much time polishing everything

A lot can be found in textbooks, but also speak with physicians, and patients

Identify their strengths and weakness, also: speaks with users



Who will embrace or resist your new medical technology?

Not only the size and growth, but also the segmentation, trends…

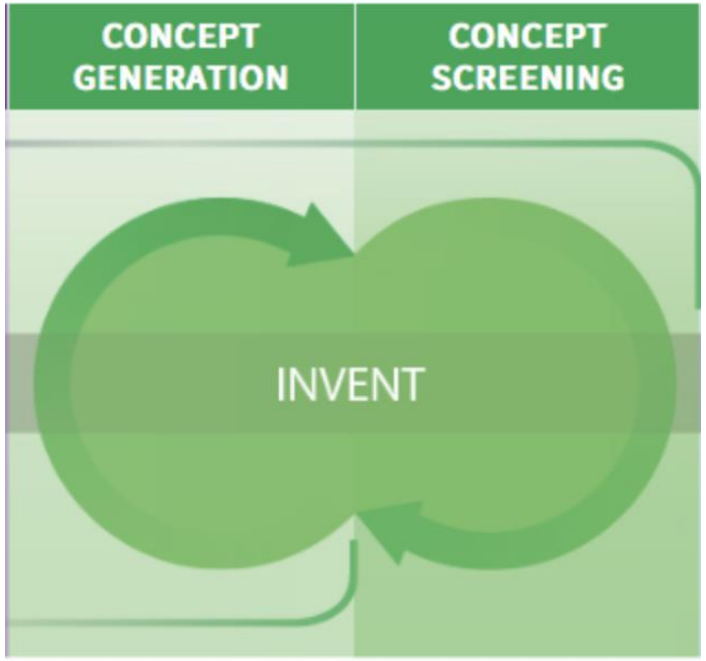
Typically, apply a semi-quantitative ranking of needs

i.e., the diabetes need is ranked very high because:

- **Size of the problem**: Diabetes affects +800m people worldwide, and the number is steadily increasing
- **Accessibility and affordability**: Current solutions are invasive, expensive, and have short lifetime (2 weeks)
- **Clinical benefit**: Improving glycemia is proven to prevent disease progression

Be ready to “kill” 90% of your ideas. Be laser-focus while still being agile and ready to change

Now, it’s time to invent



At this stage:

- **Concept generation** is about design ideation and initial concept selection
- Generate as many concepts as possible through brainstorming sessions
- Critically assess each design:
    - Technology risk?
    - Development risk?
    - Time and cost?
    - Resources, expertise needs?

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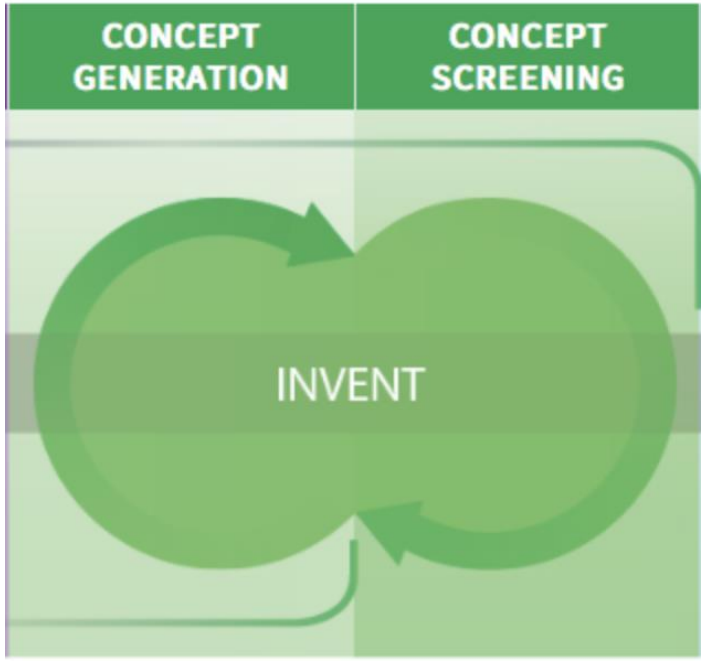


At this stage:

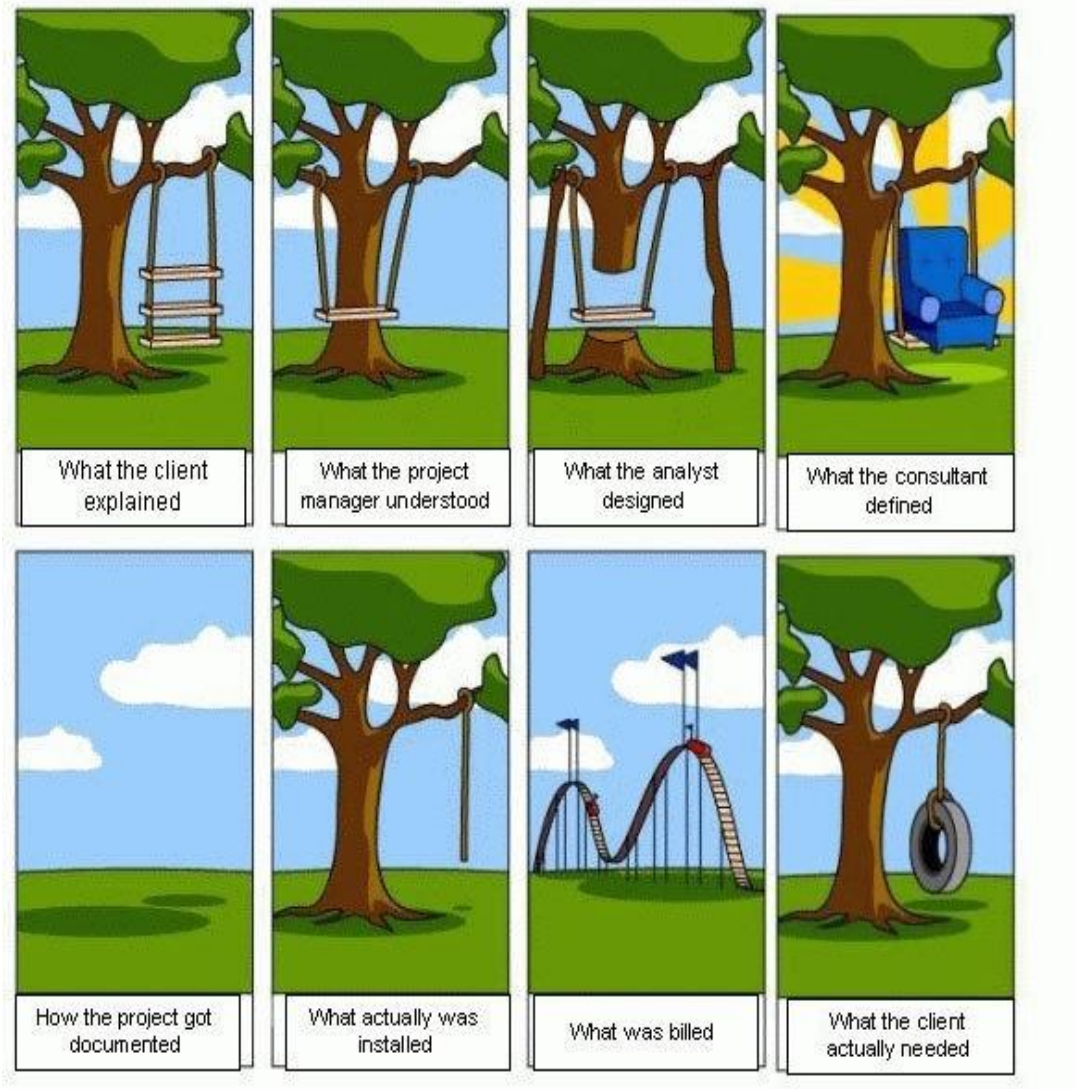
- **Concept generation** is about design ideation and initial concept selection
- Generate as many concepts as possible through brainstorming sessions
- Critically assess each design
    - Technology risk?
    - Development risk?
    - Time and cost?
    - Resources, expertise needs?
- **Concept screening** is about performing a series of evaluation (basic at this stage) of:
    - Intellectual property landscape
    - Regulatory landscape
    - Reimbursement models
    - Business models
    - …

Iterative, cross-functional work
The first round is a matter of hours/subject

Product development now starts

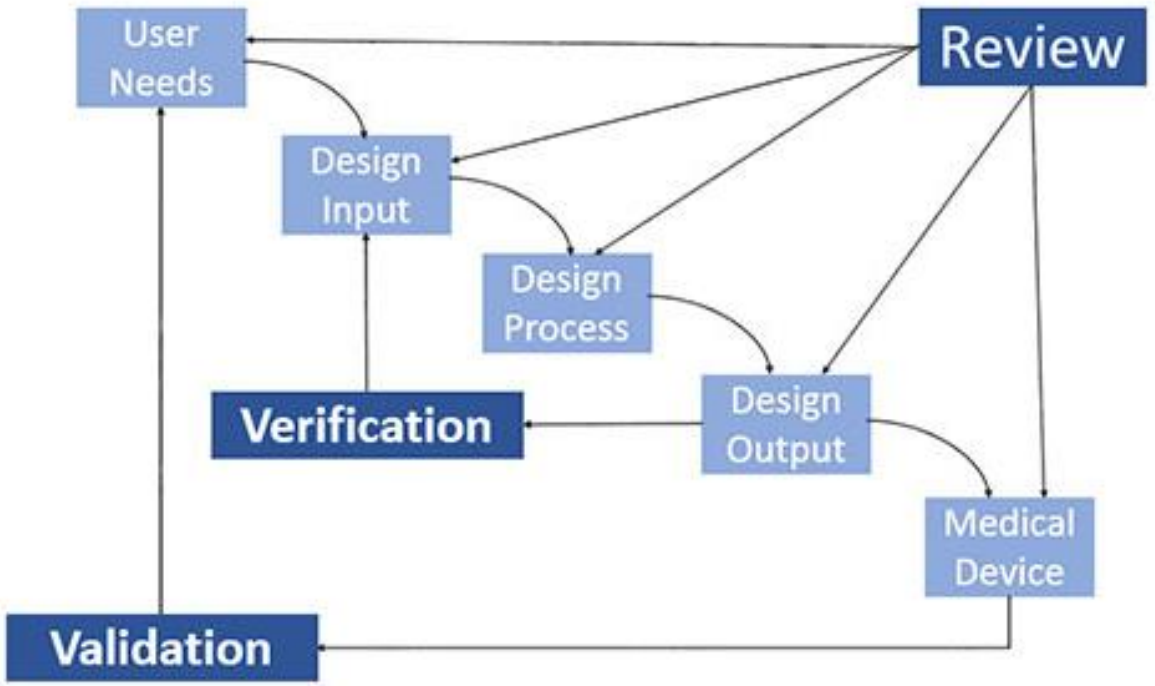
At the core is the concept of Design Control and requirements management

Design control aims at ensuring (i) swift development, and (ii) that the customer gets what was desired



Design control is described in ISO 13485 [(1)] and provides guidance on how to develop safe and effective medical devices

At the core of the standard: Design Control



A stepwise process with checkpoints to ensure the final product meets the product you wanted to develop

Design input

- Translation of customer/market needs into (measurable/quantifiable) technical requirements.

Design Process

- Develop the product according to plan. Design Outputs describe all the components, parts, and pieces that go into your product.

Verification

- Making sure that you have objective evidences that specified requirements ("inputs") are met ("outputs"). ("you have developed the product right")

Validation

- Makes sure that the product conforms to End User requirements and application. → The product is validated in simulated conditions where its actual performance is tested (e.g., clinical testing of medical devices). ("you have developed the right product")

(1) ISO 13485 – Medical devices — Quality management systems — Requirements for regulatory purposes

Design input: translate market/customer needs into product requirements

Building on the “need identification” from earlier, you can now write what the device will be and do

- Listen to the customers, know the market’s needs, grasp the market trend
- Translate these learnings into product requirements
- Design and plan carefully

Customer says (“market needs”)	Scientist / Engineers must understand (”requirement specifications”:
“More accurate than current method”	Sensitivity > 85% and sensitivity > 90%
“I need something that allows me to have a normal life, to go out, exercise, etc”	IP67 and pass IEC 61010-1 drop tests
“Faster than current methods”	Time to result < 5 minutes
“Use a small amount of blood”	Require <50 ul of blood

A requirement must be objective, unambiguous, testable, measurable

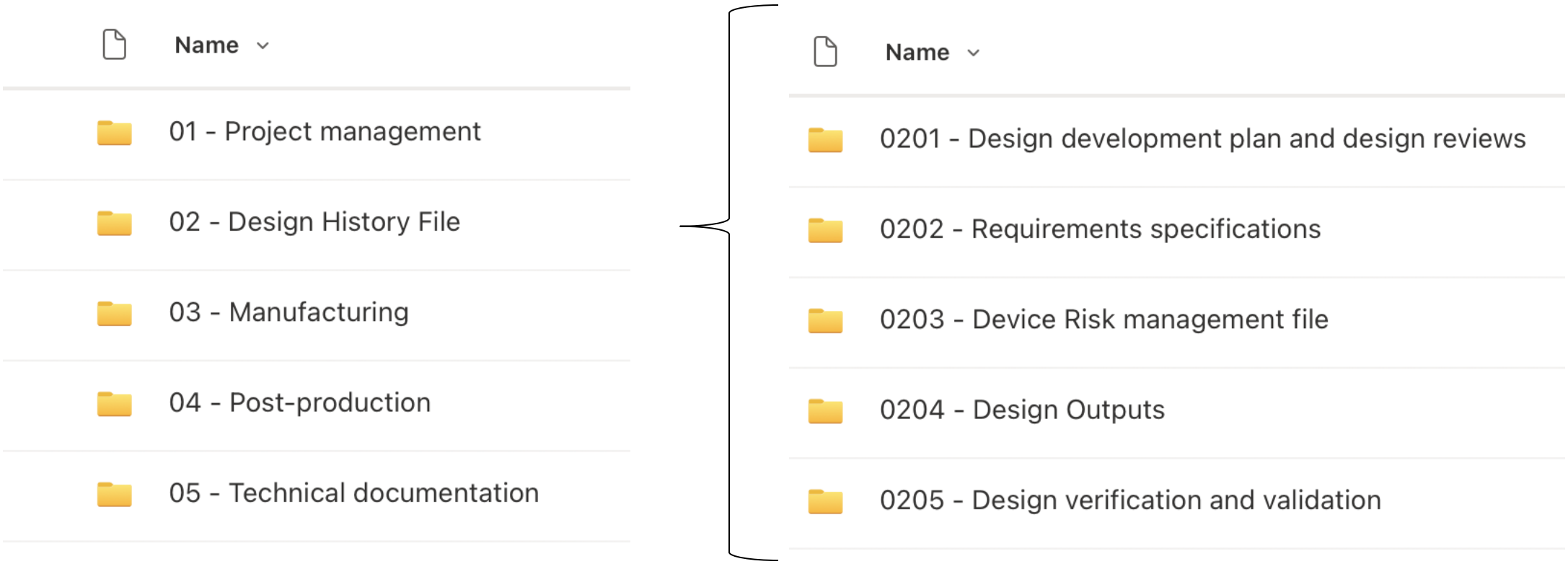
Design input: translate market/customer needs into product requirements

Requirement Specification							
Specification	ID	Ref.ID	Title	Description	Explanation / Origin	*Parent R ID*	*Child Req. ID*
Technical Specification	006	TS-P-006	Laser power	The system shall contain an internal laser power sensor for measuring the laser power	Ensure the correct laser power for data quality Risk ID: P2025-003-DFMEA-03, -04- and -23	*URS-F-001*	*TS-F-0021, TS-P-007, TS-F-022*
Technical Specification	021	TS-F-021	Laser power range	The internal laser power detector shall have a maximum detection range of at least 500 mW	To cover the laser system power output range	*TS-F-001*	-
Technical Specification	007	TS-P-007	Laser power precision	The laser power meter shall have a measurement uncertainty below 5%	Verification based on the product specification sheet Risk ID: P2025-003-DFMEA-04, -05- and -23	-	-

Requirements are:

- Written and version controlled
- Explained
- Traceable User requirement > product requirement > tech requirements
- Linked to risk management (for implementation of risk control measures)

… and it really happens in real (industry) life!



A product cannot be successful if it doesn't respond to a need

Example of a wrong understanding of customer needs

Problem: Pathogens causing severe infections are often identified too late to timely start the right antimicrobial treatment

Solution? Iridica. Combined PCR/ESI-MS for faster pathogen identification

→ Technology acquired for USD 250m by Abbott Laboratories
→ Commercialised in 2014
→ Removed from the market in 2017:
- Too expensive (device, reagents)
- Low throughput not meeting labs needs

→ not meeting customer (hospital) needs

Part I – wrap-up

- Spend the right amount of time identifying and selecting a match between market need/opportunities and new solutions addressing this need that you can develop
  - Iterative process – favour efficiency and value creation over perfection
    - You will learn more along the way – walk the thin line between being laser-focused on your next objective while keeping the agility to make a 180° shift
    - Accept that 90% of your ideas will not be pursued
- Seek a diversity of opinions
- When you enter product development – make sure you work against clear requirements

PART II

– Fundamental in bioassay development –

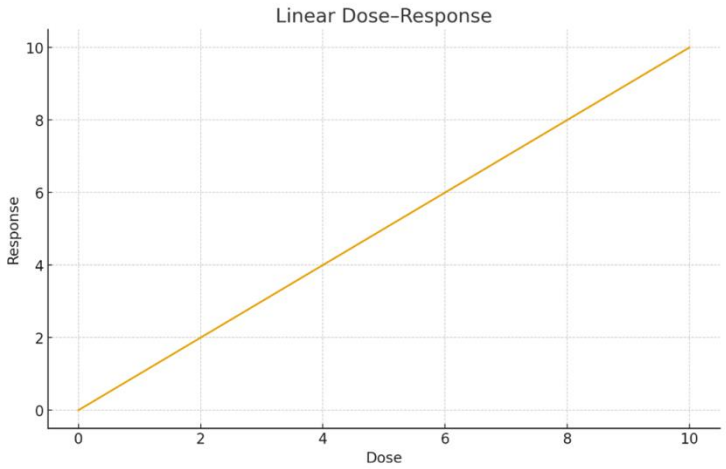
Let’s start with the basics

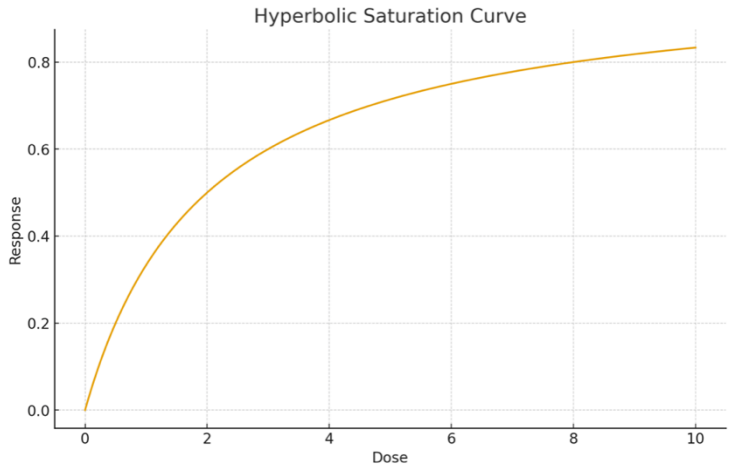
We focus on ligand binding assay with non-linear dose-response, as in protein-protein / cell-based assays

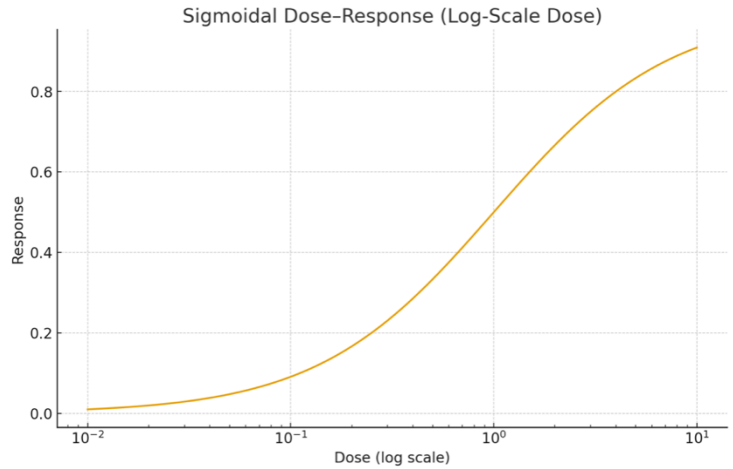
- When Response = k ·[analyte] → linear relationship (pH, conductivity, Bradford assay…)
- When the assay relies on saturable processes (e.g., binding sites), the response is not linear and produce hyperbolic/sigmoid dose-response relationships (Ag-Ab, ligand-receptor…)

$$K_d = \frac{[L][R]}{[RL]} \qquad Fraction\ occupancy\ (R) = \frac{[L]}{[L]K_d}$$

→ “good” affinity gives a low K_d





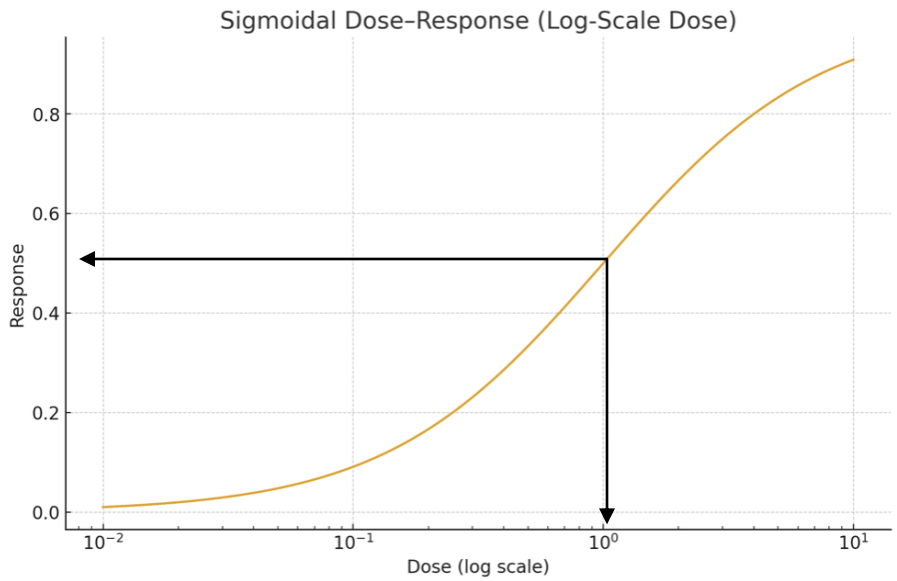


(Semi-log scale)

Let’s start with the basics

”Good” receptors have high affinity for their ligand, expressed by a low K_d

- The K_d is he dissociation constant, which is the concentration of the ligand at which the receptor is 50% occupied



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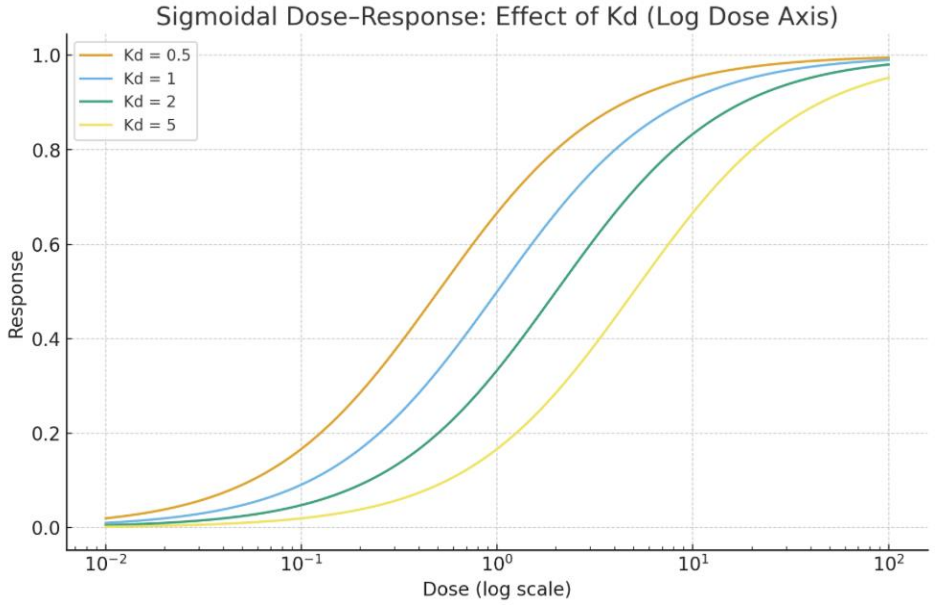
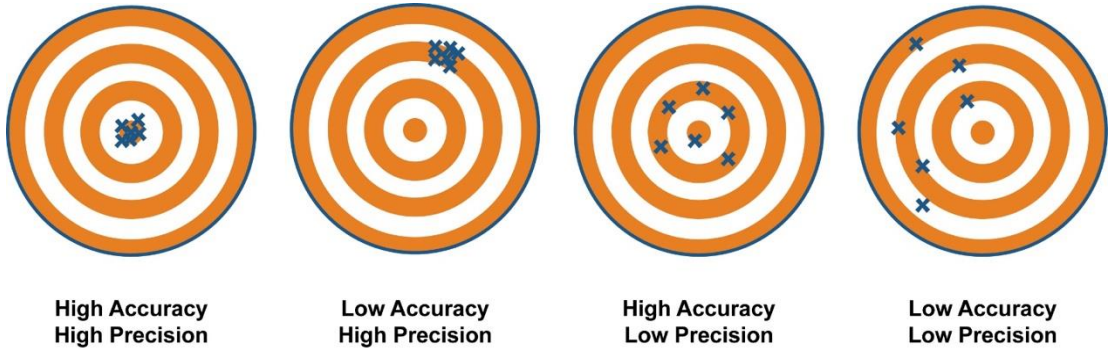
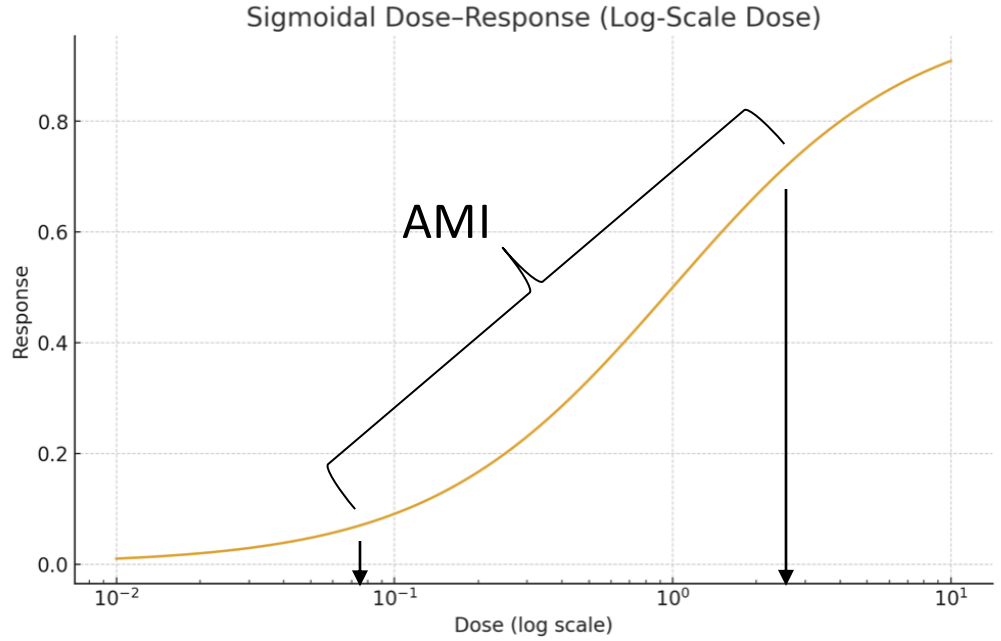


At the core of any assays are the concept of “accuracy” and ”precision”

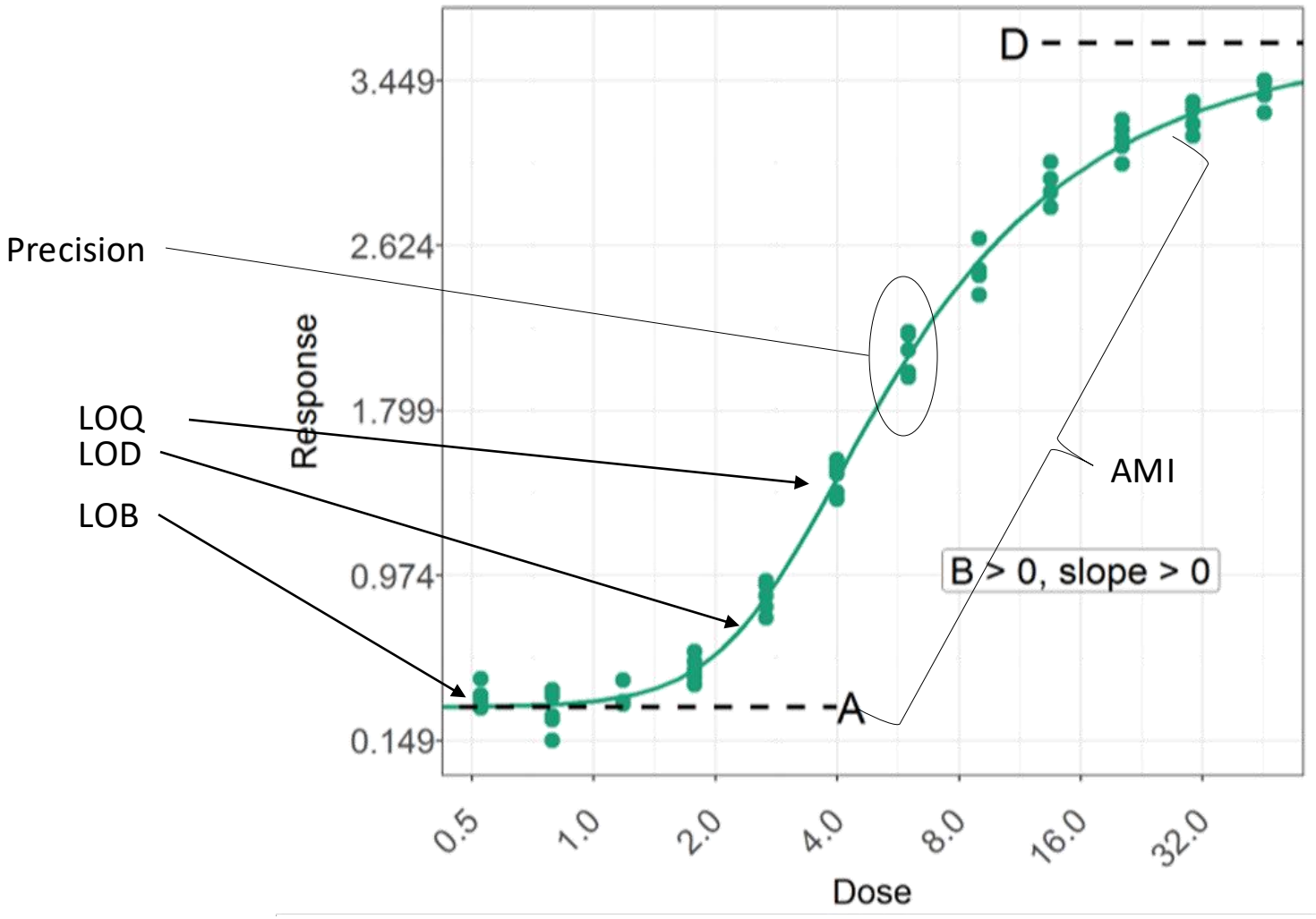
- **Accuracy**: the closeness of agreement between a test result and the accepted reference value (“bias + random error”)
- **Precision**: closeness of agreement between independent test results obtained under stipulated conditions (“random variation”)
- **Assay measurement interval** (AMI) : the span of concentrations where the assay’s analytical performance is verified and meets acceptance criteria (of precision and accuracy, usually)





Dose-response and calibration curves

You can estimate several key assay characteristics from a calibration curve

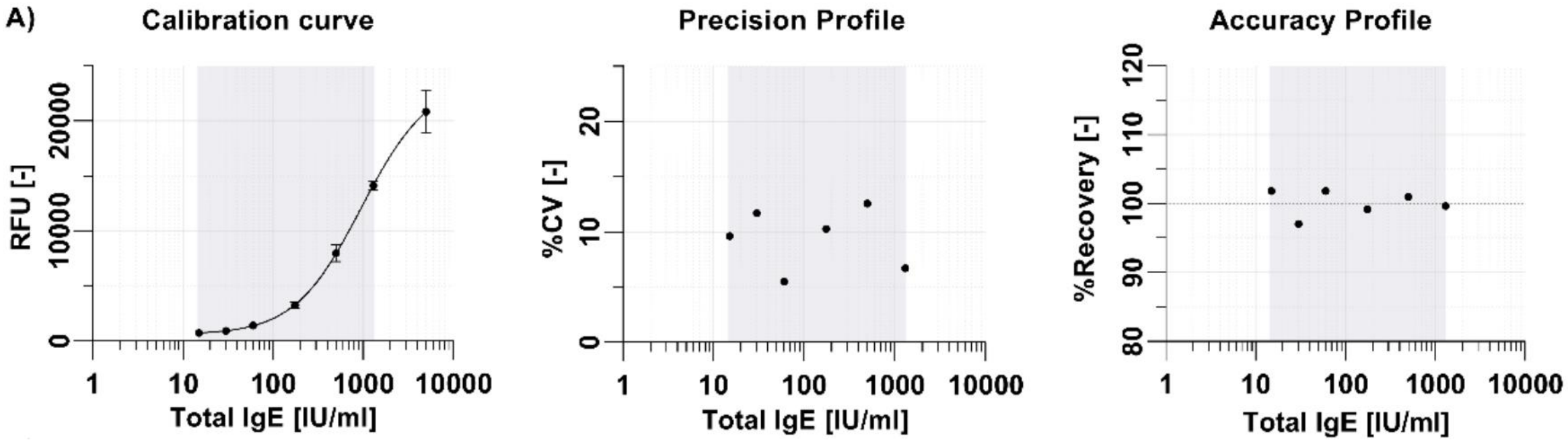


- A "dose-response curve" is how the system's response change in function of the dose
- When the instrument response is used to assign an unknown quantity from a measurand, it must be "calibrated"

Source: www.quantics.co.uk

Most development work is around dose-response curve

Calibration of ligand binding assay (LBA)



- Fitting strategy is also about selecting right doses, number of replicates, applying weighting strategy, anchor dose, forcing the fit through a specific dose…
- Validate your fitting strategy's performance over a sufficiently large number of independent data set
- Keep the biochemical mechanisms and mathematical logic in the loop!

Source: Putallaz et al., 2019

Without “good” calibration, no chance to have a “good” assay

Calibration of ligand binding assay (LBA)

Practically speaking:

- First of all: start by looking at your data and think about your need, your system, your biomolecule before running into complex analyses!
- Quickly screen key assay parameters by running calibration curves (reagents selection, sample dilution, capture / detection reagent concentration…)
- Run high-density calibration curves (including doses above and below anticipated upper and lower detection limits), until an apparently acceptable assay range is obtained.
    - Typically, end-up with 5 to 8 doses (for 4- or 5-PL model)
    - Perform calibration with each dose in duplicate or triplicate (depending on your repeatability)
- Choose the best fit and calibrator doses, based on established precision and accuracy goals.
    - Typically, 4-PL or 5-PL models should be the most appropriate ones
    - Wisely apply weighting and anchor points if (and where) necessary
    - Optimise accuracy (%RE) and precision (%CV) where it makes the most sense (i.e., around medical decision points)

Recommended reading to go further:

Calibration of ligand binding assay (LBA)

Recommended “guides” to calibration (freely available on the web):

The AAPS Journal (2018) 20: 22
DOI: 10.1208/s12248-017-0159-4

White Paper

Calibration Curves in Quantitative Ligand Binding Assays: Recommendations and Best Practices for Preparation, Design, and Editing of Calibration Curves

Mitra Azadeh,[1,7] Boris Gorovits,[2] John Kamerud,[3] Stephen MacMannis,[4] Afshin Safavi,[5] Jeffrey Sailstad,[5] and Perceval Sondag[6]

***The AAPS Journal* 2007; 9 (2) Article 29 (http://www.aapsj.org).**

Themed Issue: Bioanalytical Method Validation and Implementation: Best Practices for Chromatographic and Ligand Binding Assays
Guest Editors - Mario L. Rocci Jr., Vinod P. Shah, Mark J. Rose, and Jeffrey M. Sailstad

Appropriate Calibration Curve Fitting in Ligand Binding Assays

Submitted: February 21, 2007; Accepted: June 8, 2007; Published: June 29, 2007

John W. A. Findlay[1,2] and Robert F. Dillard[3]

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[3]BioStatistics and Data Management, Takeda Pharmaceuticals North America, Inc, Deerfield, IL

Imprecision comes from many sources (“variance components”)

Precision and accuracy

Source of imprecision:

- Within-run (not applicable to single-plex assays)
- Between-run
- Lot-to-lot, device-to-device…
- Day-to-days, Operators-to-Operators, site-to-site…

The goal of between-run precision (immunoassay): the lower, the best

- For most measurands, <10% is ok (20% at LOQ)
- For most assays on large clinical laboratory analyzers, imprecision is often << 10%
- But, in the end, it is all about the clinical need and risk linked to imprecision

The design of precision studies is often complex quite resource-demanding

Precision and accuracy

The experimental design

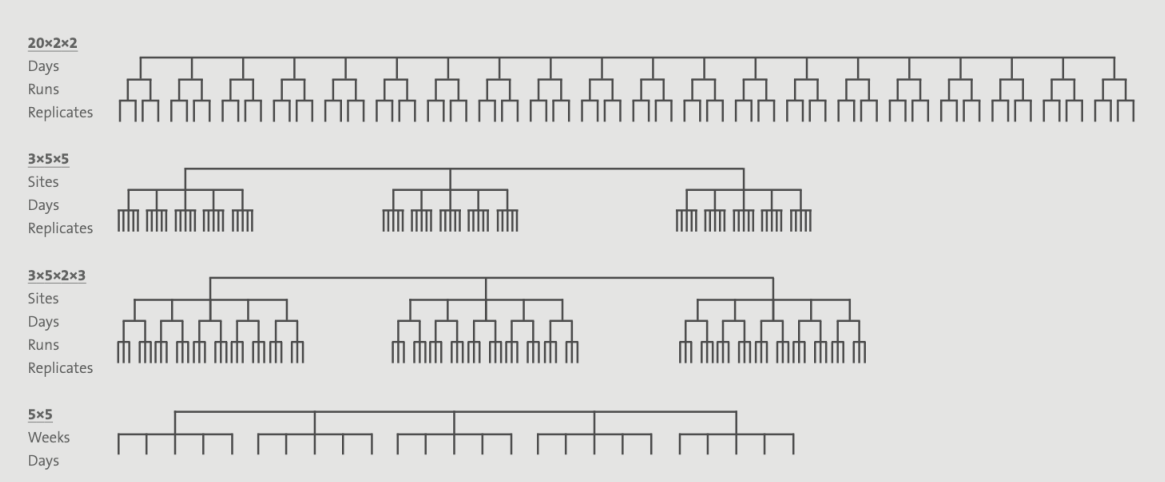


Figure 3. "Comb" Diagrams. These represent the standardized single-site 20 × 2 × 2 experimental design, the standardized multisite 3 × 5 × 5 and alternate 3 × 5 × 2 × 3 designs, and (see Figure 2) the QC-like 5 × 5 design used by way of illustration. All are nested (or hierarchical) structures; eg, in the 20×2×2, replicates are nested within runs, and runs within days. And all are balanced designs. The first and second designs each involve two factors—days and runs for the 20×2×2, sites and days for the 3×5×5—hence both designs are amenable to analysis by two-way nested ANOVA. The last two designs involve three factors and one factor, respectively, corresponding to three-way nested and one-way analyses.

Outcome presentation

PSP Dose [ng/ml]	N [-]	Mean [ng/ml]	SD [-]	CV [%]
Low	10	49.5	2.3	7.2
Intermediate	10	110.8	10.8	8.0
High	10	176.8	25.4	11.5
Average imprecision				8.9

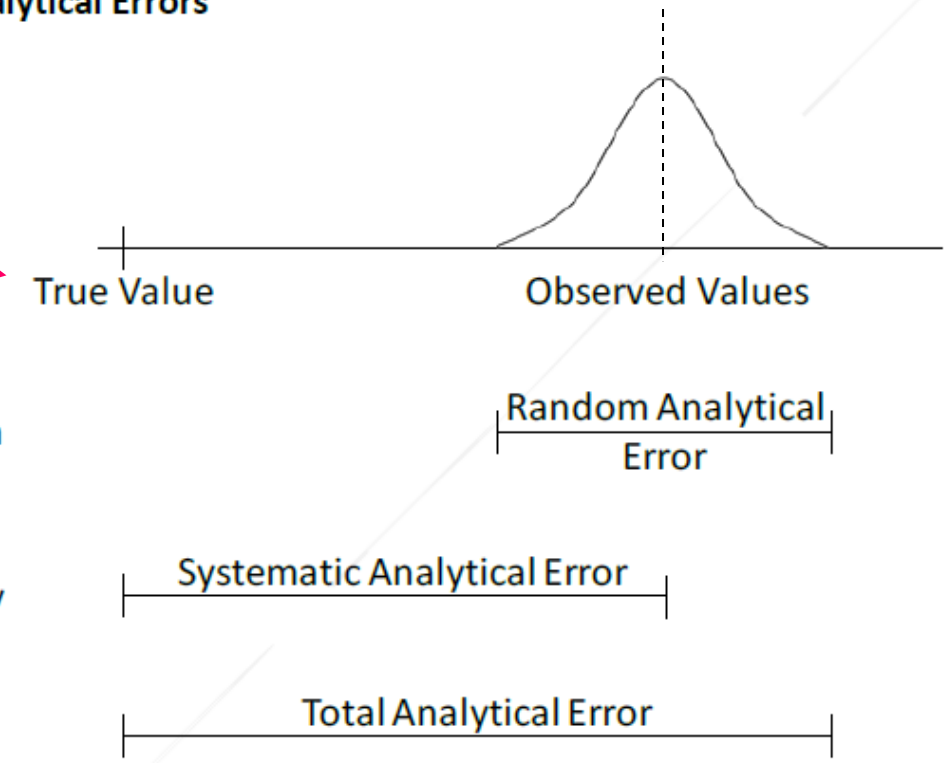
Table 1 | Between-run imprecision of the PSP assay on the abioSCOPE device. The average between-run imprecision, calculated as the mean coefficient of variation issued from 10 replicates obtained on a same device with a same lot, was 7.2% for a low dose sample, 8.0% for an intermediate dose sample and 11.5% for a high dose sample. PSP: Pancreatic stone protein, N: Number of replicates, SD: Standard deviation, CV: Coefficient of variation.

Sources: CLSI EP05-A3 and Abionic PSP White paper (2019)

Combining precision and accuracy = total error

Precision and accuracy: total analytical error

Figure 1: Definitions of Precision and Accuracy in terms of Random, Systematic and Total Analytical Errors



Note: for new biomarkers, the "true" value cannot always be easily determined!

In new technologies, precision is often a challenge…

… because it's new. Because now it's often low concentration. Because you do not have time to optimize

Practically speaking (*my advices*):

- During early development, focus on multiple replicates over a couple of days to quickly get a first estimate of precision
- Brainstorm and test hypotheses regarding the presumed sources of imprecision (also consider pre-analytical steps – particularly relevant for near-patient testing (think about the challenge of nasopharyngeal swab in SARS-CoV-2 testing)) and manufacturing
- If acceptable and need to go through extensive verification study: dig into CLSI EP05-A3 and/or seek help of specialists
- When speaking of assay performance, precision values usually come in first or second place (with assay reportable range). It highlights how important it is to reach the goal for precision

Bioassays can be influenced by the presence of non-target molecules

Analytical Selectivity ("Interference testing")

- Interfering substances can be a significant source of error in (clinical) measurements. Such errors may, in some cases, represent a hazard to the patient

- Endogenous interference originates from substances present in the patient's own specimen.
  - Hemoglobin, bilirubin, biotin, rheumatoid factor, human anti-mouse antibodies…

- Exogenous interferences are substances introduced into the patient's specimen
  - Drugs, nutritional products
  - Substances from collection tube
  - Test sample additives such as preservatives
  - Carryover contamination

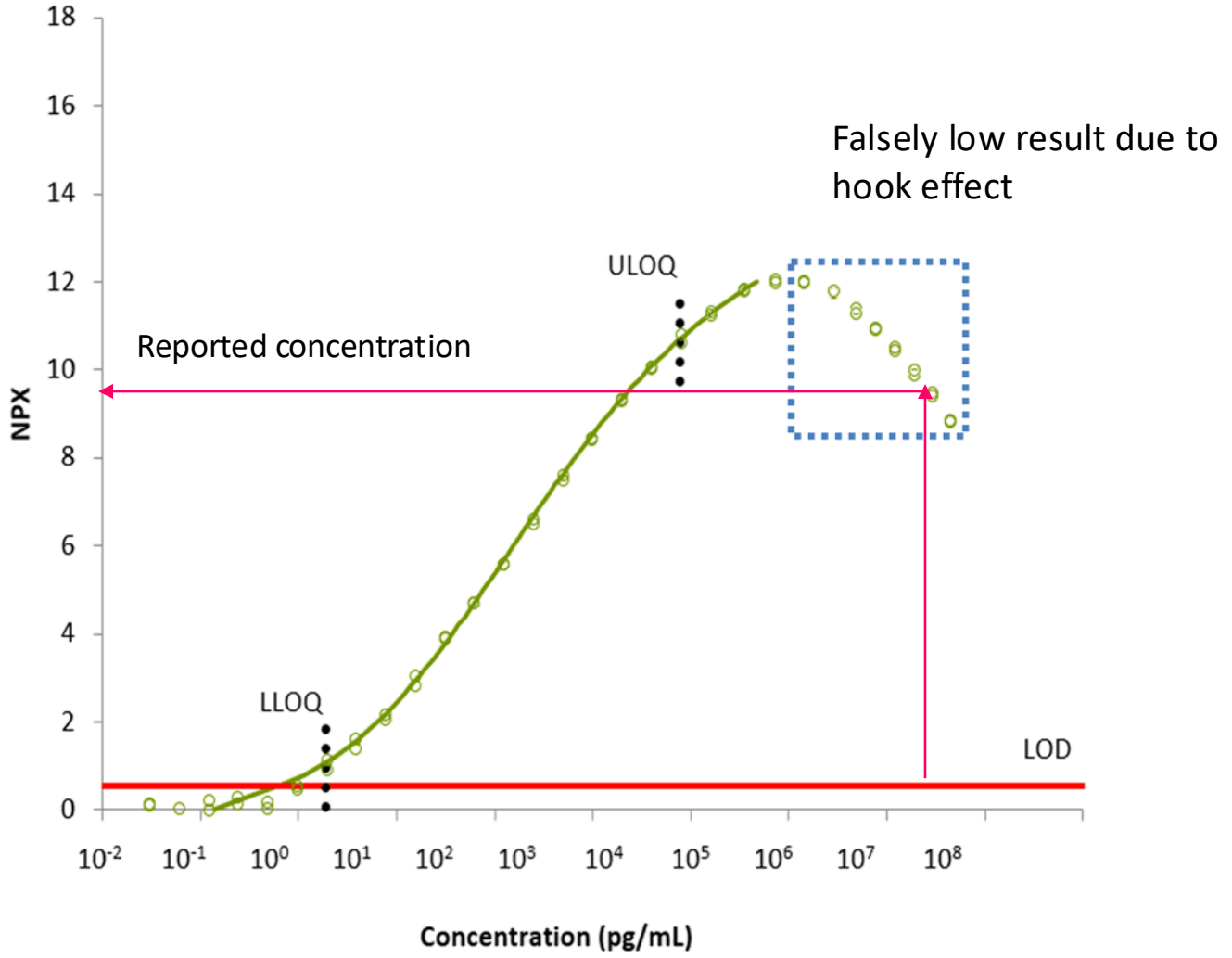
Also, extreme target analyte concentration can lead to undesired effects

Interferences

Hook Effect (analyte excess)

There is **too much analyte**, causing:

- Capture antibodies become saturated with *single* analyte molecules
- Detection antibodies also bind analyte in solution (not bound to the capture antibody)
- No sandwich forms → the system cannot produce signal
- Signal drops, giving a **false *low***

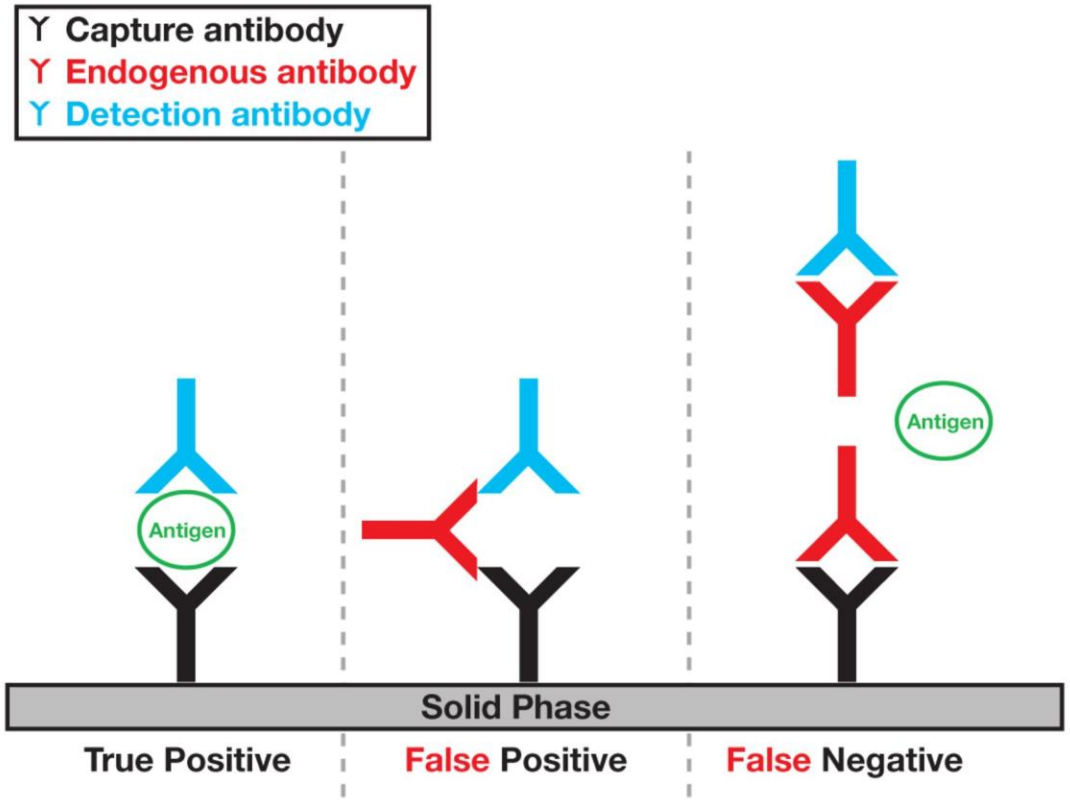


Endogenous antibodies may also interfere with a test

Interferences

Endogenous antibody interferences:

- Heterophilic antibody (*antibodies to external antigen, cross-reacting with self-antigen, typically anti-mouse antibodies)*
- Rheumatoid factor (*IgM against Fc portion of human IgG, cross-reacting with the animal counterpart*)
- Autoantibodies (e.g., anti-DNA antibodies, but also anti-drug antibodies)



academic.oup.com

An assay development perspective

Interferences

- Defining the presence of an interference:
    - Generally, a change of X% (usually 10%) from original results confirms interference
    - Sample difference is assessed by paired t-test, and if $p<0.05$ it is considered statistically significant, and interference is occurring
    - You can live with an interference… as long as it is clearly communicated and not too frequent

Practically speaking:

- Define a list of substances and their concentration to be evaluated (talk to regulation agencies)
- Analyze multiple time samples with / without the potential interfering substance at several concentration, including clinically elevated
- Blot the bias (absolute and/or relative) versus the analyte concentration for test samples and control samples

Part III

Innovation in medical device product

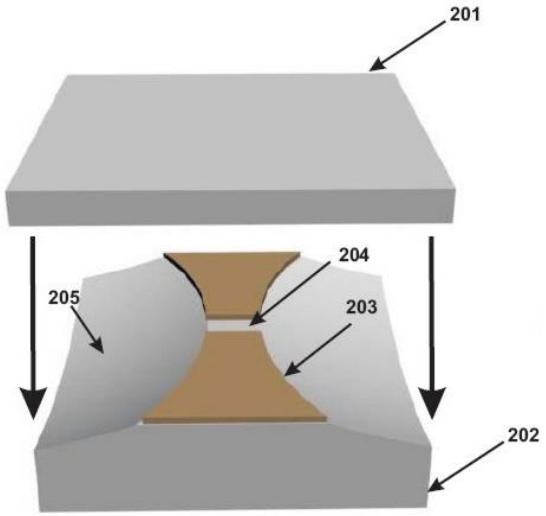
Practical examples:

(i) **Nanofludic-based immunoassay (Abionic SA)**

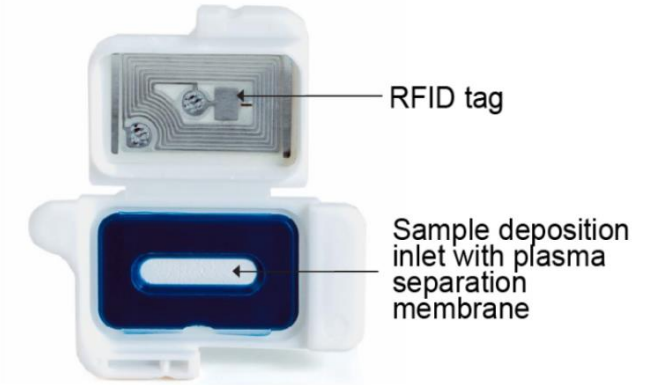
(ii) **Non-invasive glucose sensing (Liom Health AG)**

Nanofluidic is the study of the behavior, manipulation, and control of fluids that are confined to structures of nanometer

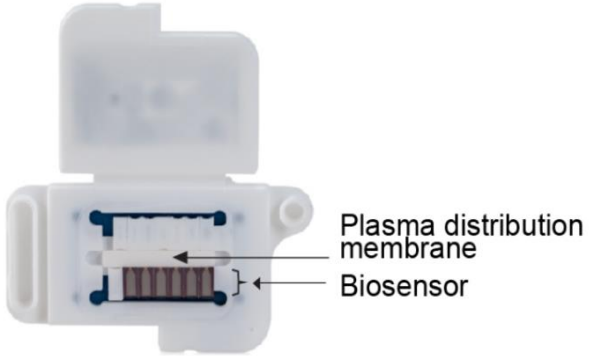
Nanofluidic-based point-of-care platform for immediate, actionable test results



Nanofludic biosensor



Top view



Bottom view

Source: Abionic SA

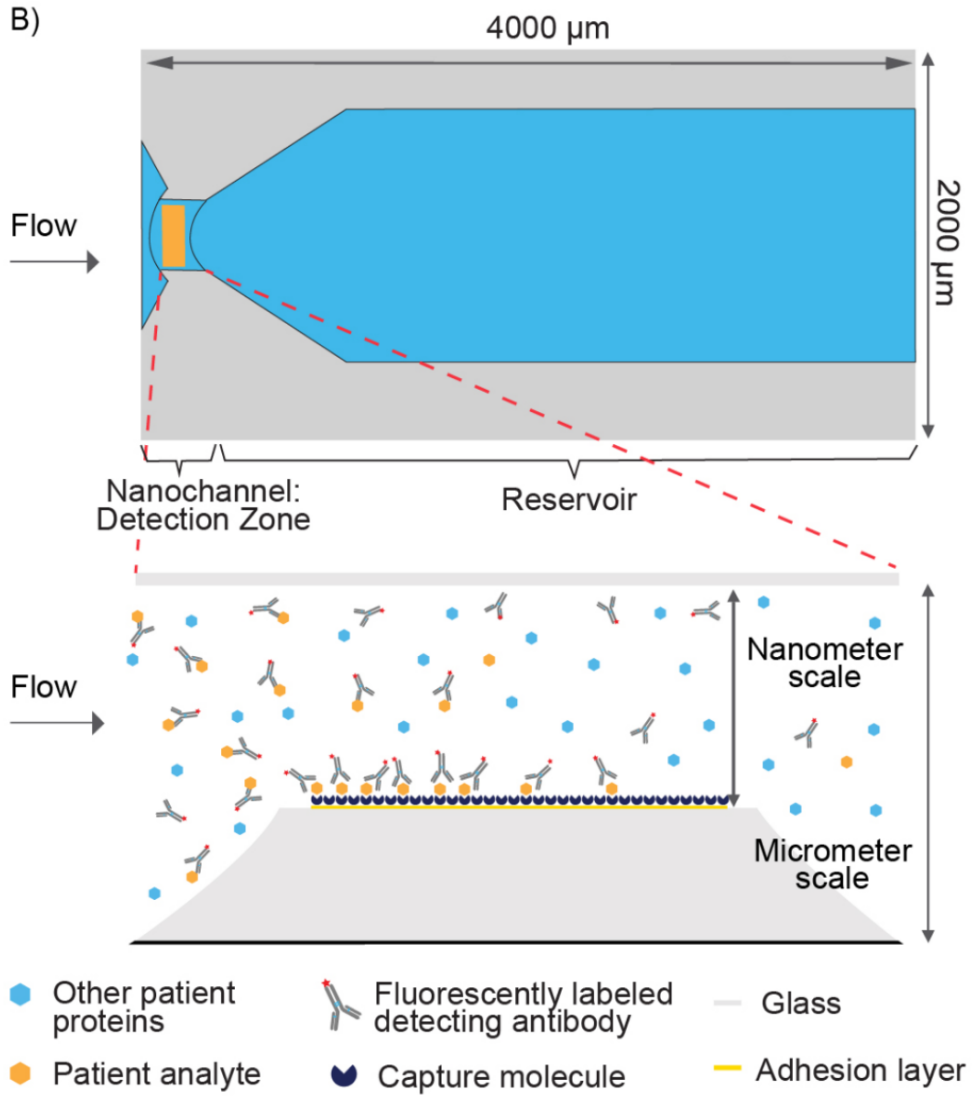
Nanofluidic is the study of the behavior, manipulation, and control of fluids that are confined to structures of nanometer

Rapid binding kinetics due to increased surface area over volume ratio

Capture chamber volume is several thousands of times smaller than a microtiter well:

→ non-specific background signal is negligible

→ washing step is not required

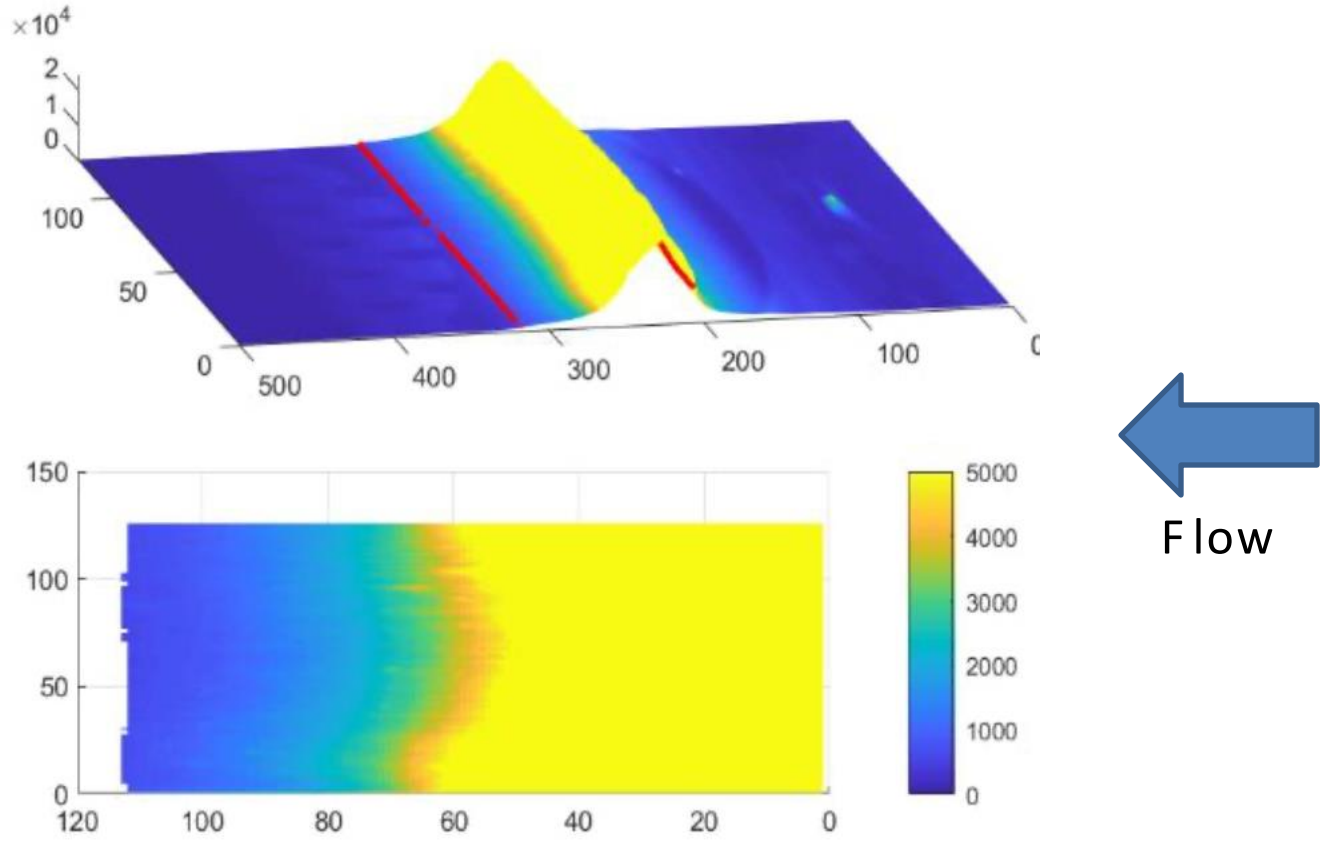


Source: Abionic SA

Nanofluidic is the study of the behavior and manipulation of fluids that are confined to structures of nanometer

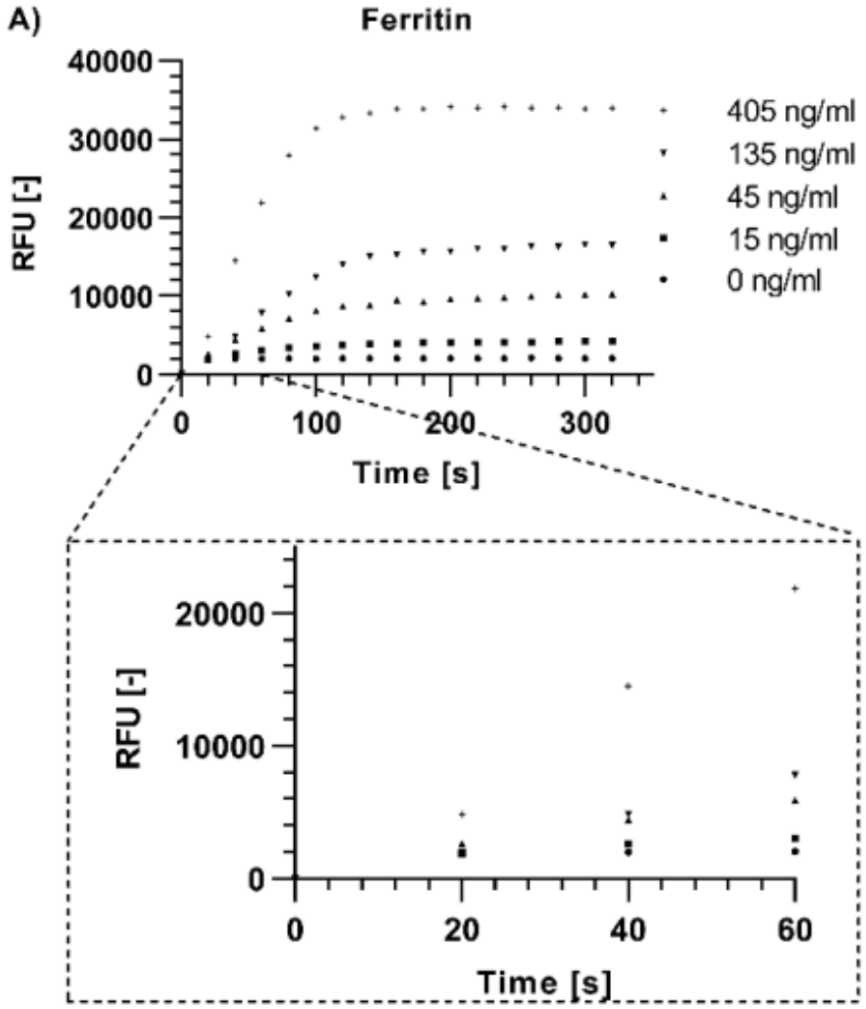
The technology proof of concept (Putallaz et al., 2019)

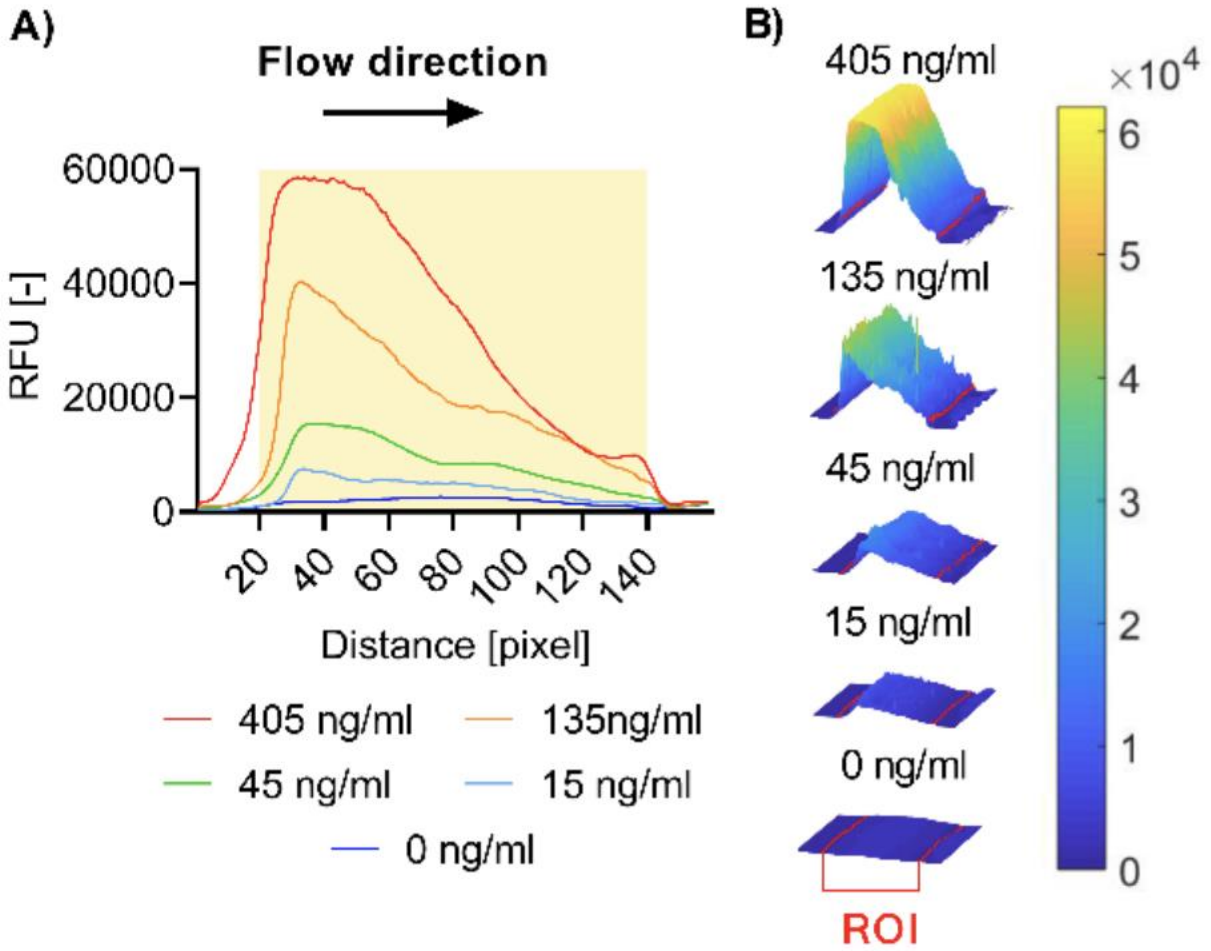
- Rapid binding kinetics
- Near-100% capture efficiency thanks to increased surface area over volume ratio and selection of high avidity antibodies.



Source: Puttalaz et al., 2019

Nanofluidic is the study of the behavior, manipulation, and control of fluids that are confined to structures of nanometer





Source: Putallaz et al., 2019

Abionic – from an idea to a market-fit product

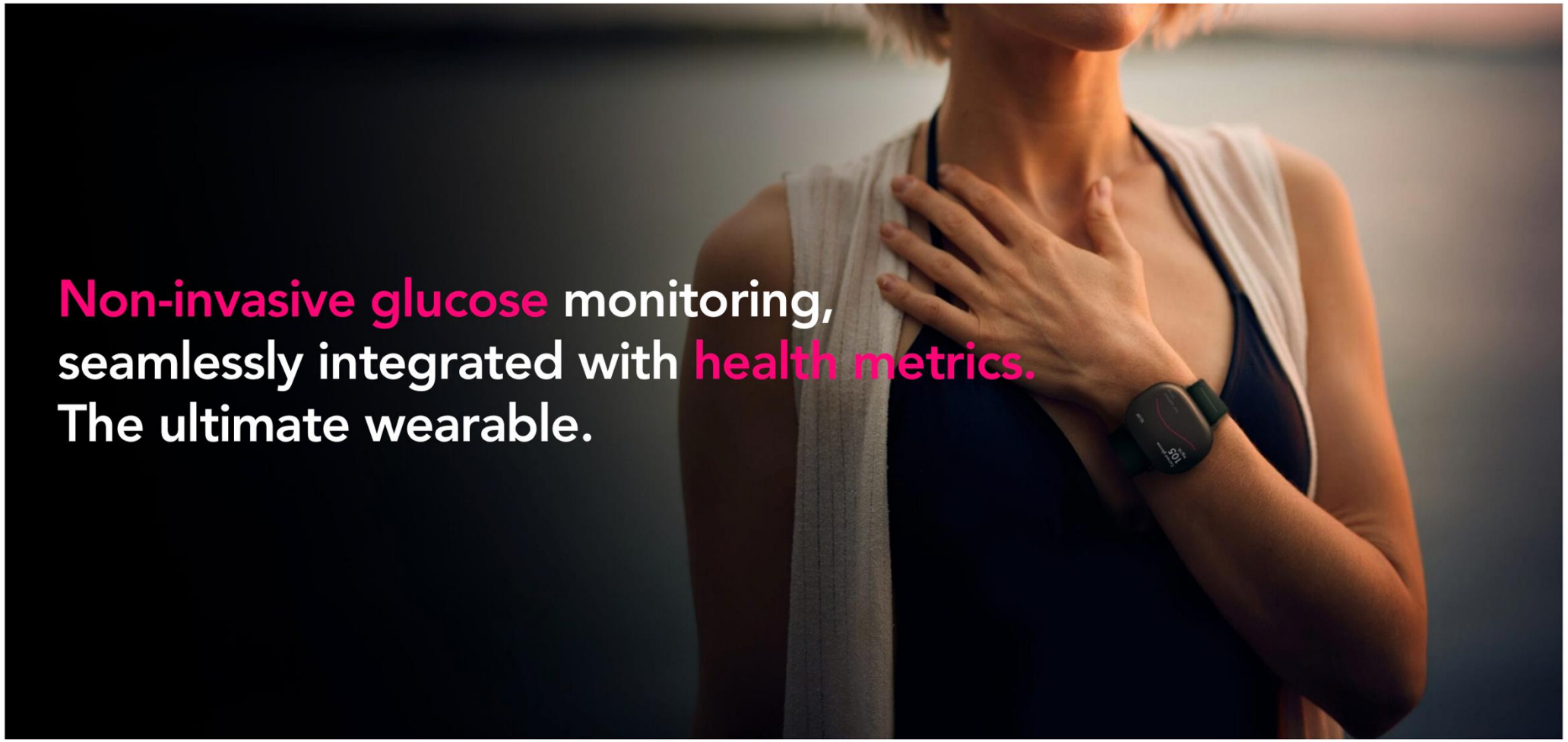
- 2010 – Founded as a spin-off from EPFL
- 2012 – Tech proof-points and ISO 13485 certification
- 2020 – Sepsis test is CE-IVDR marked, start commercialization in Europe
- 2024 – Sepsis test is FDA cleared, start commercialization in the US

Some of my learning (8 years in the company (2012-2020), from 4 to 50+ FTEs, from idea to product):

- I wish I would have been aware of the Biodesign book
- Development takes (often / always) more time than planned – and don't believe than market entry with a prototype-stage device is a good idea
- Medical devices are about people health – adoption takes time; expected level of evidence of safety and efficacy is tremendously high – plan accordingly
- The multidisciplinary aspect of the MedTech industry makes the journey memorable – I've learnt so much!
- Such a good idea to go out and speak to doctors, patients, policy makers… do it early. Never stop doing it

Source: abionic.com

The quest to non-invasive, continuous monitoring



LIOM

The quest to non-invasive, continuous monitoring

LIOM'S OPEN-ENDED GROWTH OPPORTUNITY

- Calibration-free and non-invasive means precision without having to pierce the skin unlocking universal appeal
- Proven form factor + rich biochemical information + convenience = open-ended growth opportunity

Constrained by limited biophysical information

WEARABLES

ESTABLISHED WEARABLES
USD 30bn, 8% CAGR

fitbit GARMIN Google WATCH

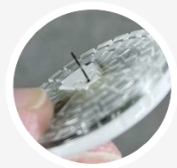
EMERGING HEALTH WEARABLES
USD 300m

WHOOP ŌURA

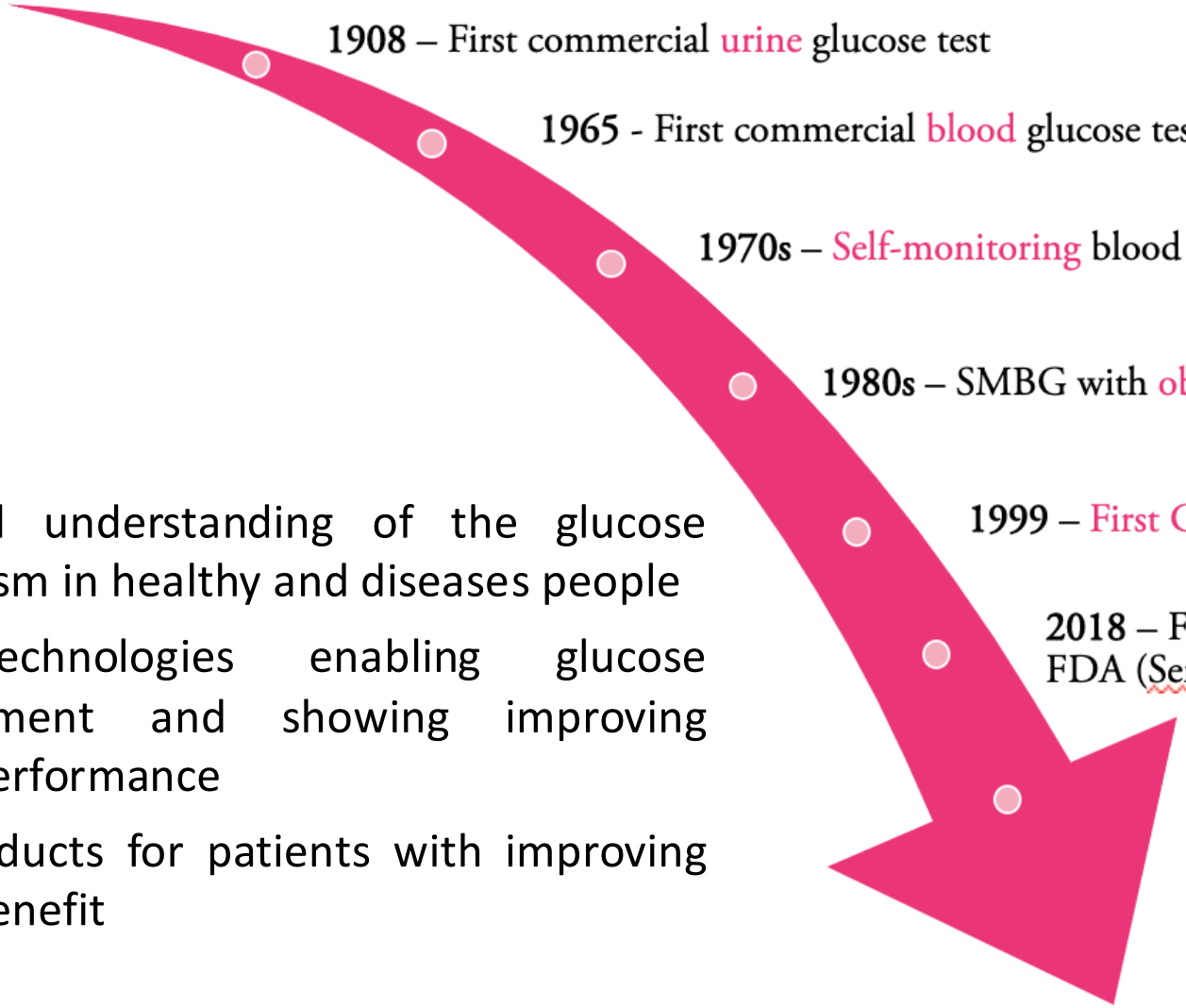
Constrained by invasive needles

CONTINUOUS GLUCOSE MONITORING (CGM)
USD 10bn, 13% CAGR

Abbott
dexcom
Medtronic



The history of glucose measurement is tightly bound to technology advancement and scientific understanding



1908 – First commercial urine glucose test

1965 - First commercial blood glucose test

1970s – Self-monitoring blood glucose monitor system (SMBG) (visual, color change)

1980s – SMBG with objective reading (electrochemistry-based)

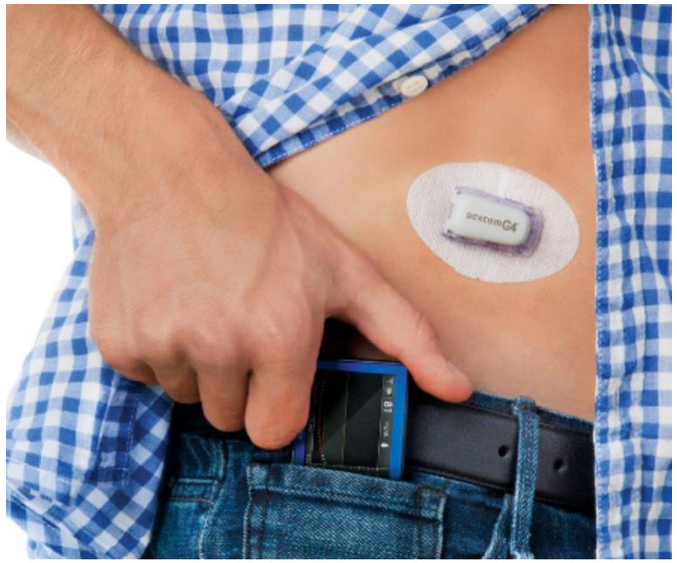
1999 – First CGM device approved by the FDA (Cygnus' GlucoWatch)

2018 – First implantable CGM device approved by the FDA (Senseomic Eversense)

2020 - First FDA approved close loop system (Medtronic Minimed, CGM + insulin pump)

- Improved understanding of the glucose metabolism in healthy and diseases people
- New technologies enabling glucose measurement and showing improving clinical performance
- New products for patients with improving clinical benefit

The history of glucose measurement is tightly bound to technology advancement and scientific understanding



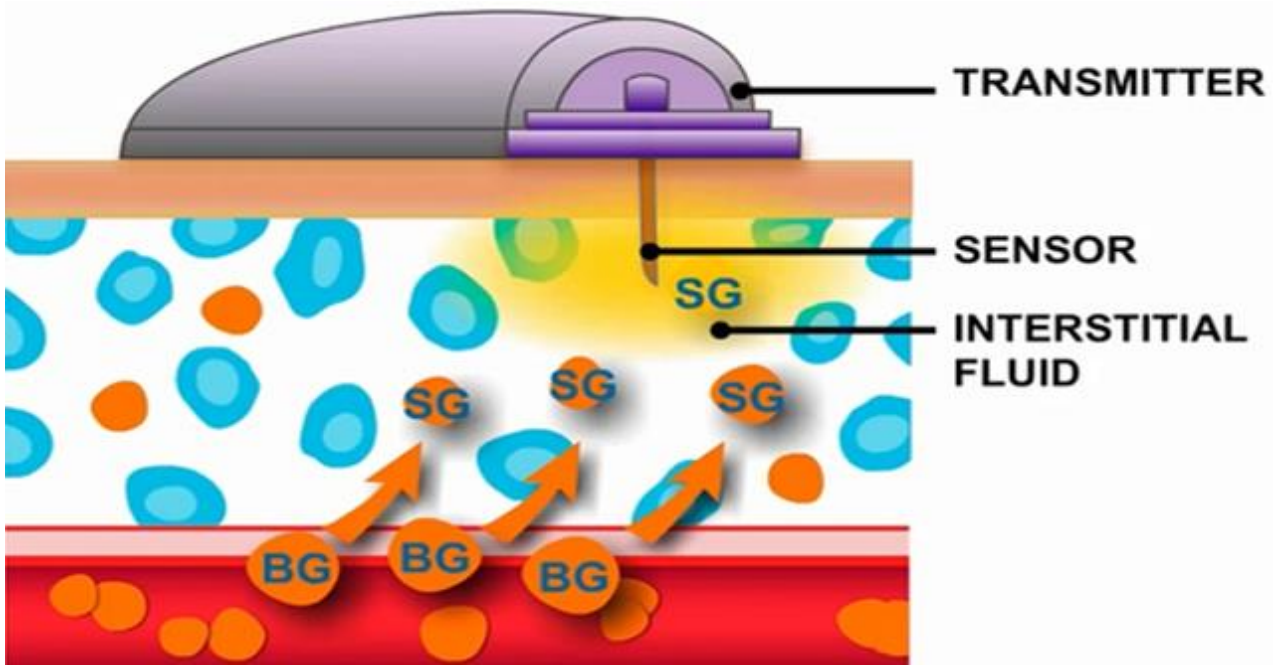
Current technologies of existing continuous glucose monitoring (CGM) rely on glucose sensing in the interstitial fluids (ISF)

Dexcom G6

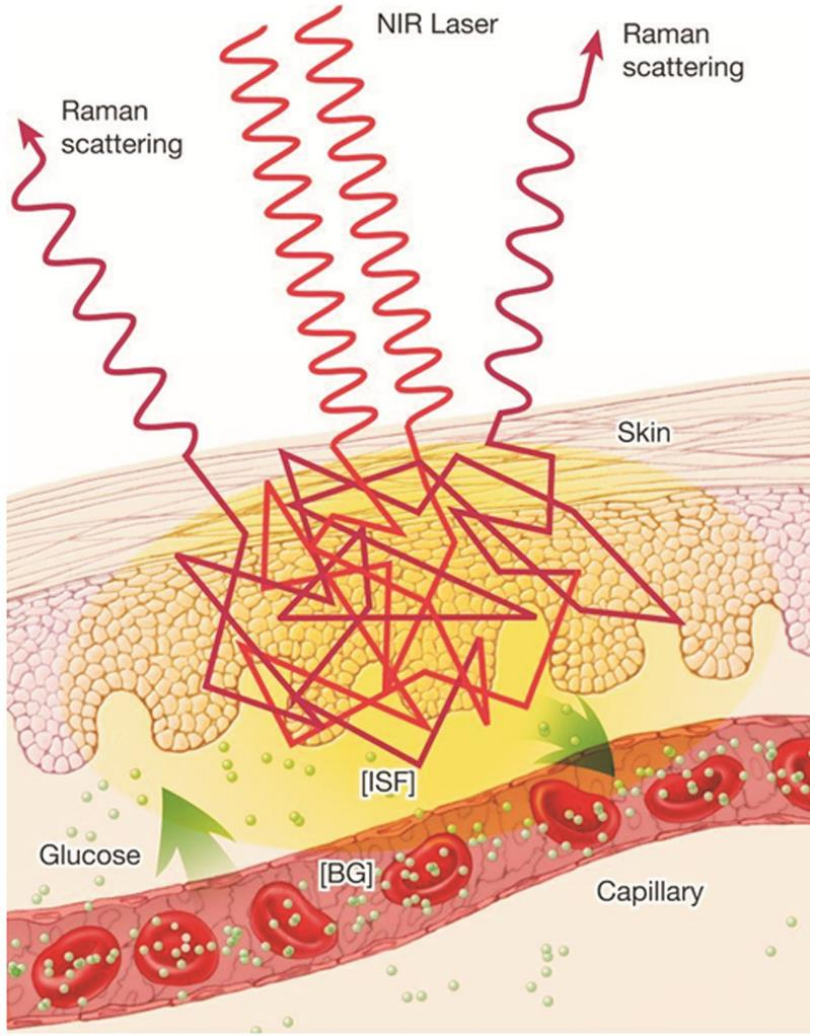
Abbott Freestyle

Medtronic Guardian

Medtrum TouchCare Nano CGM



The future will be miniaturized wearable enabling fully non-invasive, continuous sensing of glucose



Skin is a barrier that evolved to control what passes through…

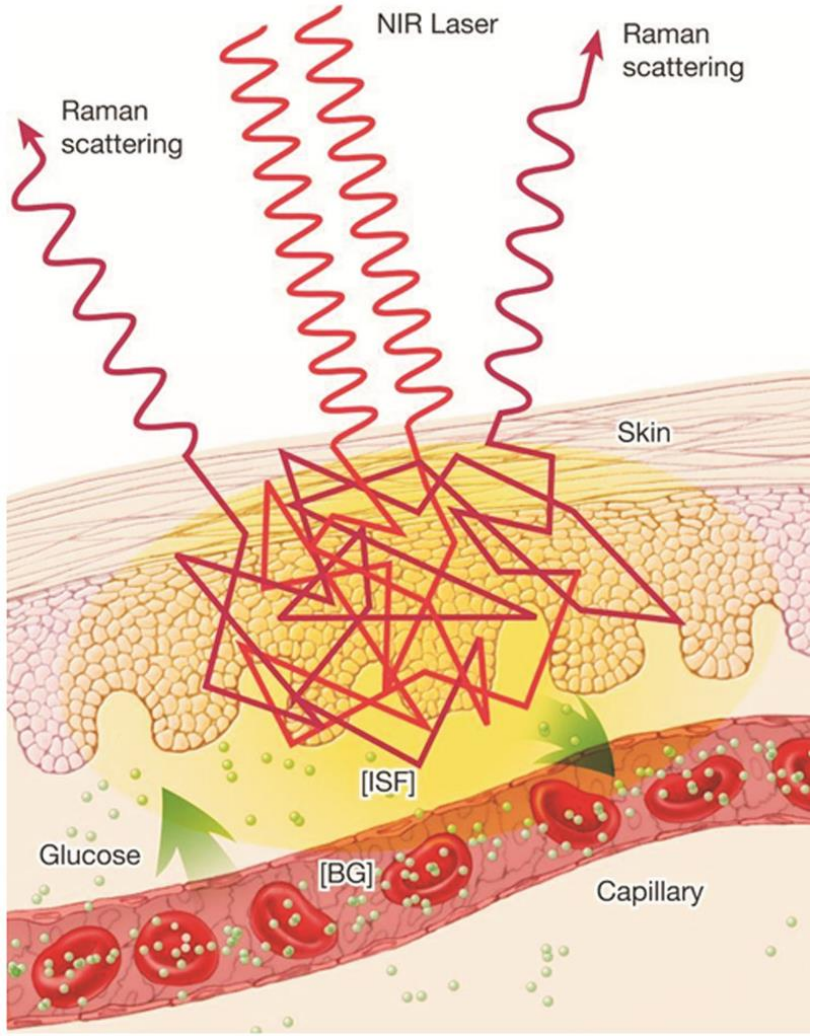
… and light is not supposed to pass through

Glucose is one molecule among thousands

Raman scattered photons are very rare

The smallest Raman spectrometer that exists today is larger and more expansive than an Apple Watch Ultra… and we must add to that a battery, a screen, other sensors… so: innovation is around all corners

The future will be miniaturized wearable enabling fully non-invasive, continuous sensing of glucose

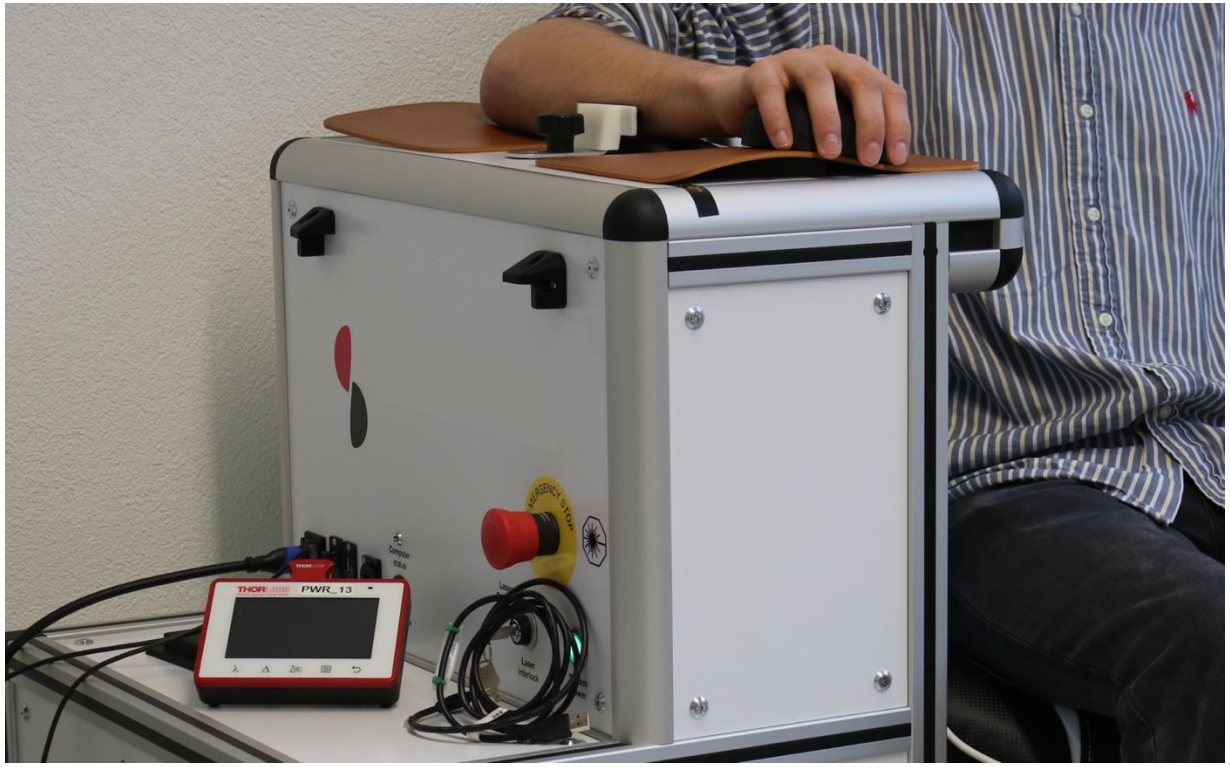


More challenges explaining why most attempts have failed so far:

- Robust person-to-person consistency, independent of skin properties (colour, thickness, hydration, skin diseases or tattoo…)
- Precision and accuracy maintained over time without any user calibration
- Analytical specificity: glucose is not isolated, so multiple cofounding signals are possible

What we have achieved so far

2022 – 2024 – Technology proof-point
« *Our tech (HW + AI/ML) can detect and track glucose non-invasively* » (Published, Rothenbühler et al., 2024, JDST)



“Pre-Development"

What we have achieved so far:

- Proof-of-concept of core technology in a large prototype
- ML model achieving targeted performances without any user calibration
- Built the multidisciplinary team that can innovate on all necessary elements

Not discussed here (yet):

- Scientific risk of miniaturization was removed
- Clear path to product

The quest to non-invasive, continuous monitoring

Journal of Diabetes Science and Technology
OnlineFirst, January 29, 2025

https://doi.org/10.1177/19322968251313811

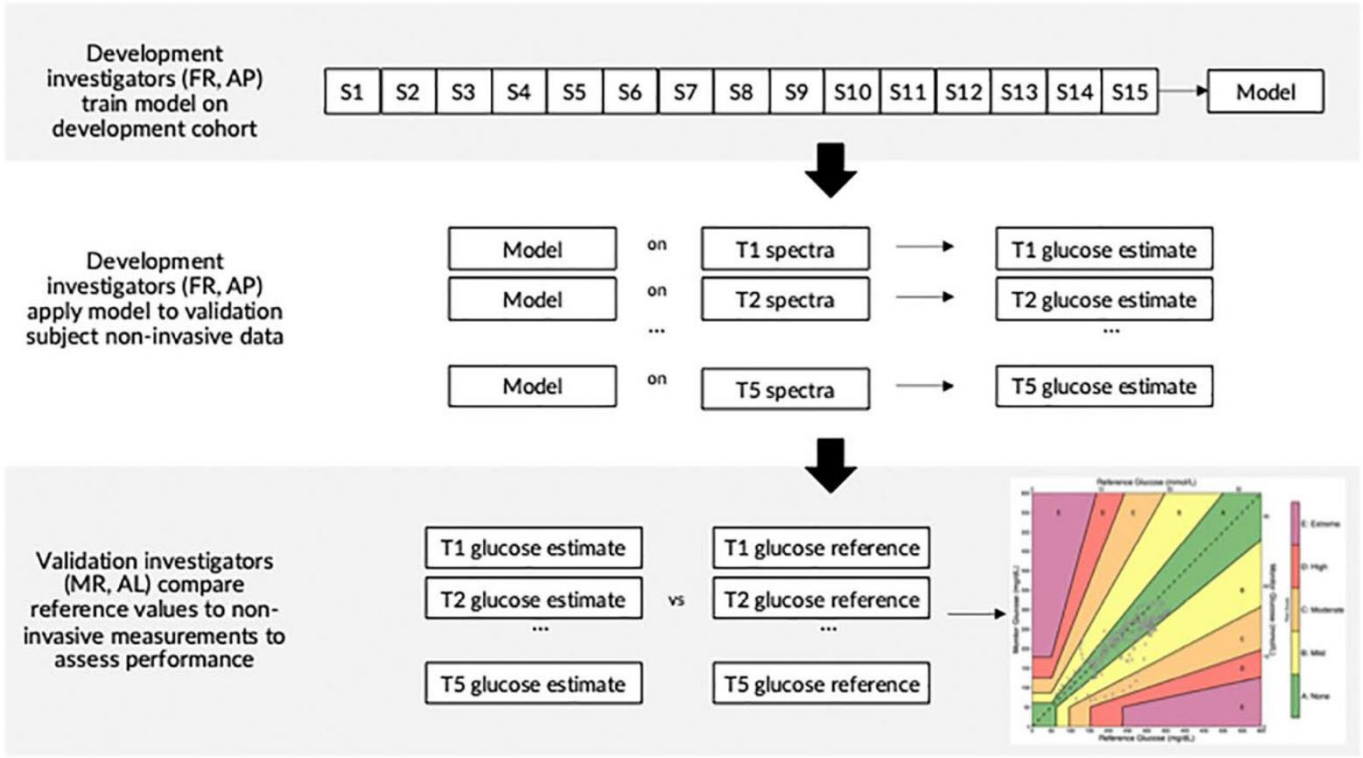
Sage Journals

Original Article

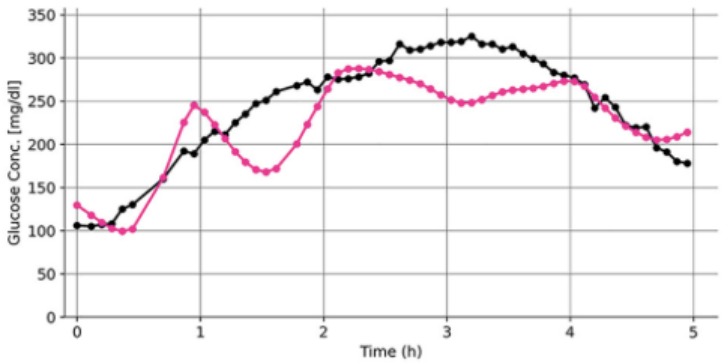
A Prospective Pilot Study Demonstrating Noninvasive Calibration-Free Glucose Measurement

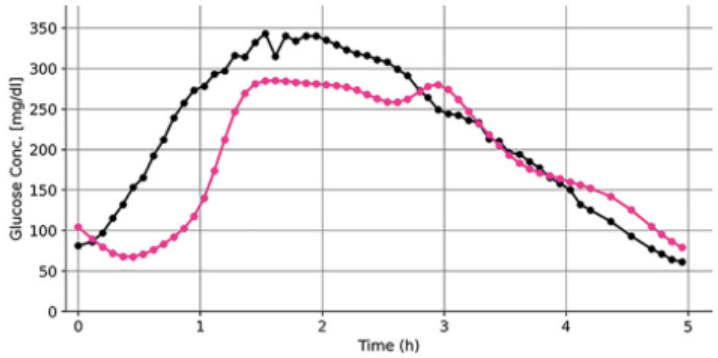
Martina Rothenbühler, PhD [1], Aritz Lizoain, MSc [1], Fabien Rebeaud, PhD [2], Adler Perotte, MD, MA [2], Marc Stoffel, PD [3], and J. Hans DeVries, MD, PhD [3]

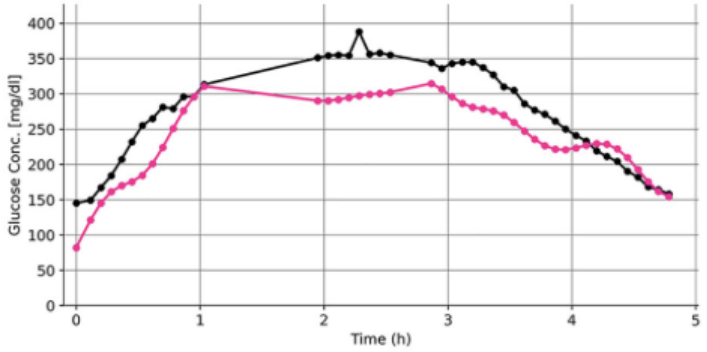
- 15 subjects for model training
- 5 for prospective validation
- No dark skin
- Glucose manipulation study covering the spectra of glucose values common found in T2D

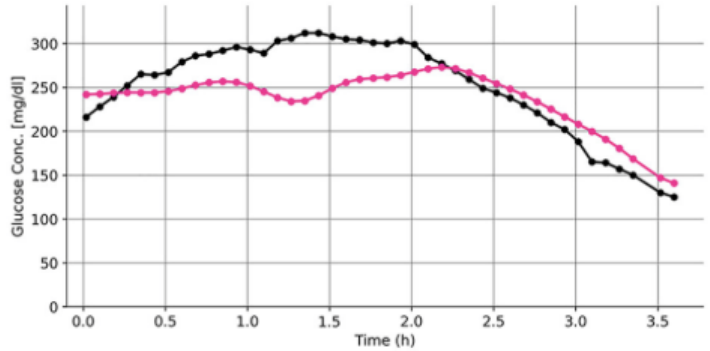


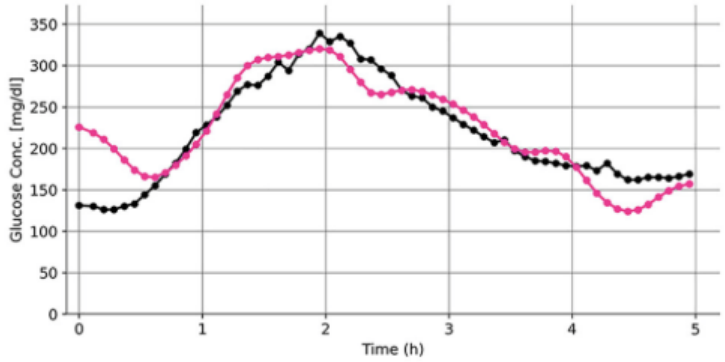
The quest to non-invasive, continuous monitoring



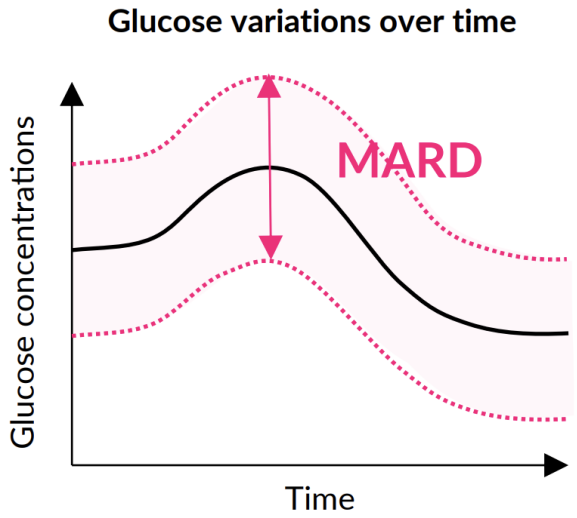






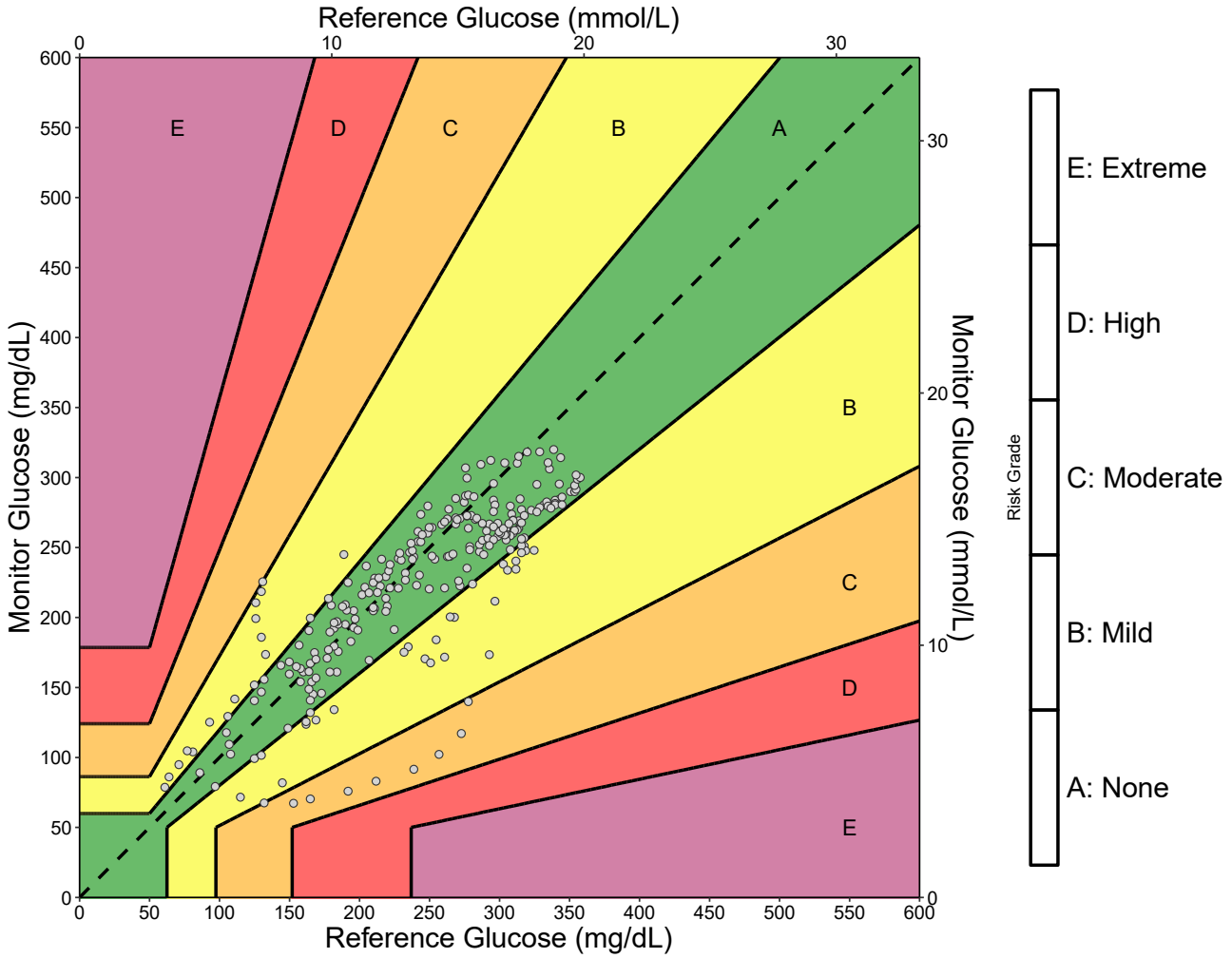


The quest to non-invasive, continuous monitoring



Mean Absolute Relative Difference

$$MARD = \frac{1}{n}\sum_{i=1}^{n} 100\frac{|Test_i - Refi|}{Ref_i}$$



MARD = 14.5%

Independent proof of feasibility

nature metabolism

Article

https://doi.org/10.1038/s42255-025-01217-w

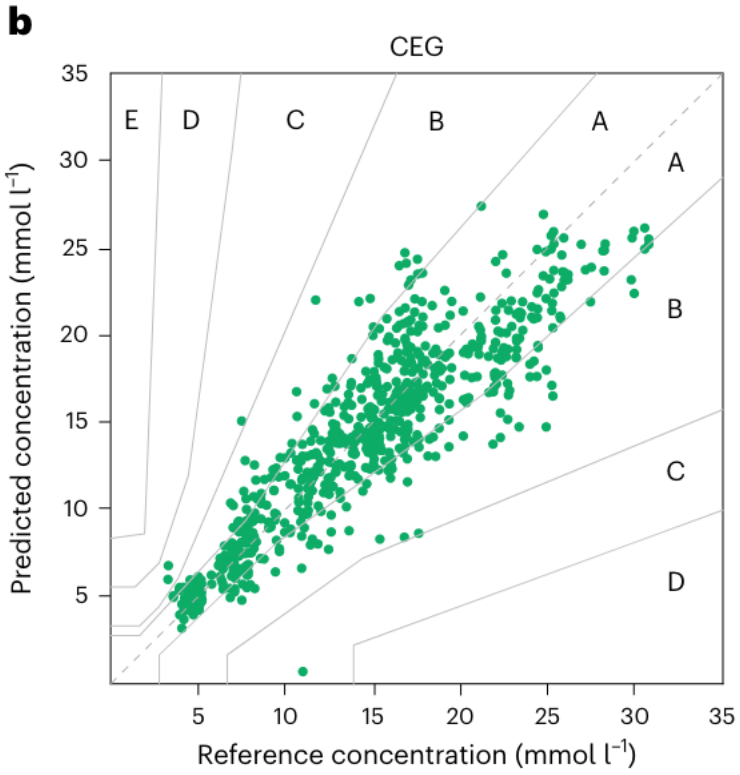
Subcutaneous depth-selective spectral imaging with mμSORS enables noninvasive glucose monitoring

Received: 7 May 2024

Accepted: 8 January 2025

Published online: 05 February 2025

Yifei Zhang[1,2,8], Lili Zhang[3,8], Long Wang[1,2,8], Shuai Shao[3,8], Bei Tao[1,2], Chunrui Hu[3], Yufei Chen[1,2], Yue Shen[3], Xianbiao Zhang[3], Shijia Pan[1,2], Hua Cao[4], Ming Sun[3], Jia Shi[1,2], Chunhong Jiang[1,2], Minghui Chen[5], Lin Zhou[3] ✉, Guang Ning[1,2] ✉, Chang Chen[3,6,7] ✉ & Weiqing Wang[1,2] ✉



MARD = 14.6% on 200 subjects

→But their tech approach is deemed unlikely to provide the miniaturization potential of Liom's one

In Conclusion

- Key message:
  - Identify high-value ideas that will make a genuine difference

    → A novelty for novelty's sake is rarely a good idea

  - Define the intended purpose of what you are developing, as well as the specifications you must reach

    → True, both in academic settings and in the industry!

  - Verify and validate that your assay/product meets what you intended to meet

  - Develop thorough technical skills and open your mind to the business, regulatory and marketing aspects of your activities

Thank you!

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