# Patient-Centric by Design:

## Lessons Learned from Developing Clinical Trial Technology with Patients

OCT DACH November 2024

# The Problem

**46%**

of those who completed a trial would encourage others to participate

**34%**

would caution peers against it[1]

We can do better at enhancing patient experiences.
**Patients can help!**

[1]DasMahapatra P, Raja P, Gilbert J, Wicks P. Clinical trials from the patient perspective: survey in an online patient community. BMC Health Serv Res. 2017 Feb 27;17(1):166

# The Potential

**87%**

**positive-results from patient-centric trials**

**68%**

**from traditional trials[1]**

Patient-centricity is not a buzzword.
**It is a NECESSITY!**

[1]State of Patient-Centricity 2020: Advancing from patient-first inventions to true co-creation, Economist Intelligence Unit Report, 2020

# The Challenges

From Paper CRFs
and Double Data Entry...

1990's

2000's

2010's

EDC

ePRO
eCOA

eSource

Risk-based
Monitoring

BYOD
eCOA

Big Data
Analytics

EHR for
eSource

Virtual Site
Visits and Tech

EHR

Consumer
Sensors

Cloud-based
Storage

eConsent

Virtual
Studies

Research
Sensors

Telemedicine
Visits

Social Media
Recruiting








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# Defining Patient Centricity

"Putting the patient first in an **open and sustained engagement** of the patient to respectfully and compassionately achieve the best experience and outcome for that person and their family."

Yeoman G, Furlong P, Seres M, et al Defining patient centricity with patients for patients and caregivers: a collaborative endeavour BMJ Innovations 2017;3:76-83.





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# First - Check the Literature!

**BMC Medical Informatics and Decision Making**

BioMed Central

Research article

Open Access

**A review of randomized controlled trials comparing the effectiveness of hand held computers with paper methods for data collection**

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**Abstract**

**Background:** Handheld computers are increasingly favoured over paper and pencil methods to capture data in clinical research.

**Methods:** This study systematically identified and reviewed randomized controlled trials (RCTs) that compared the two methods for self-recording and reporting data, and where at least one of the following outcomes was assessed: data accuracy; timeliness of data capture; and adherence to protocols for data collection.

**Results:** A comprehensive key word search of NLM Gateway's database yielded 9 studies fitting the criteria for inclusion. Data extraction was performed and checked by two of the authors. None of the studies included all outcomes. The results overall, favor handheld computers over paper and pencil for data collection among study participants but the data are not uniform for the different outcomes. Handheld computers appear superior in timeliness of receipt and data handling (four of four studies) and are preferred by most subjects (three of four studies). On the other hand, only one of the trials adequately compared adherence to instructions for recording and submission of data (handheld computers were superior), and comparisons of accuracy were inconsistent between five studies.

**Conclusion:** Handhelds are an effective alternative to paper and pencil modes of data collection; they are faster and were preferred by most users.

nature medicine

Consensus Statement

https://doi.org/10.1038/s41591-024-02827-9

**Recommendations to address respondent burden associated with patient-reported outcome assessment**

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Check for updates

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Patient-reported outcomes (PROs) are increasingly used in healthcare research to provide evidence of the benefits and risks of interventions from the patient perspective and to inform regulatory decisions and health policy. The use of PROs in clinical practice can facilitate symptom monitoring, tailor care to individual needs, aid clinical decision-making and inform value-based healthcare initiatives. Despite their benefits, there are concerns that the potential burden on respondents may reduce their willingness to complete PROs, with potential impact on the completeness and quality of the data for decision-making. We therefore conducted an initial literature review to generate a list of candidate recommendations aimed at reducing respondent burden. This was followed by a two-stage Delphi survey by an international multi-stakeholder group. A consensus meeting was held to finalize the recommendations. The final consensus statement includes 19 recommendations to address PRO respondent burden in healthcare research and clinical practice. If implemented, these recommendations may reduce PRO respondent burden.





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# Patient Insights Board

The Patient Insights Board (PIB) includes nine patient advocate board members who participate in Patient Design Studio Workshops.

Together, they evaluate trial processes, technical solutions, patient-facing materials, trial burden, sensors, and devices.





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# Patient Design Studios

Patient Design Studios are interactive workshops with our Patient Insights Board members.

In addition to regular internal design studios to inform our software development process, Patient Design Studios offer our clients and partners the opportunity to engage in a series of activities to fully understand patient perspectives and preferences for a proposed clinical trial offering.



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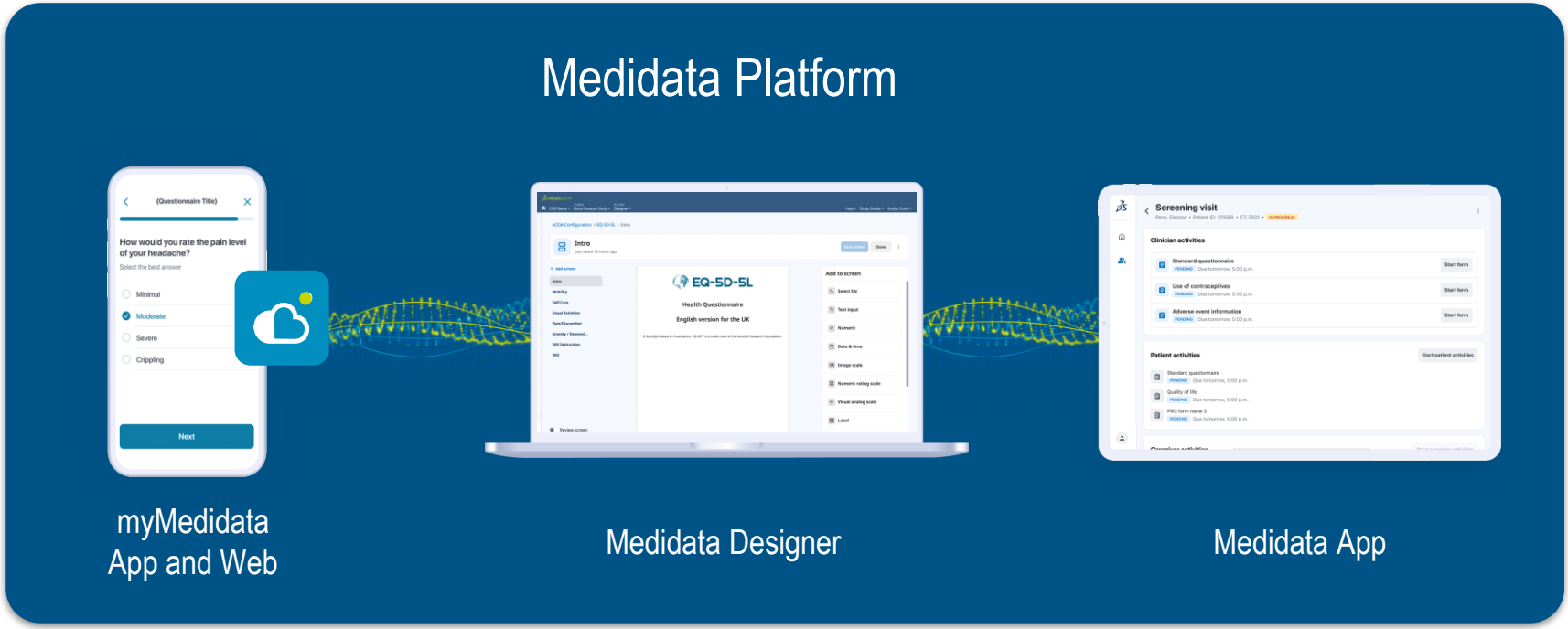
# Medidata's eCOA (and beyond)

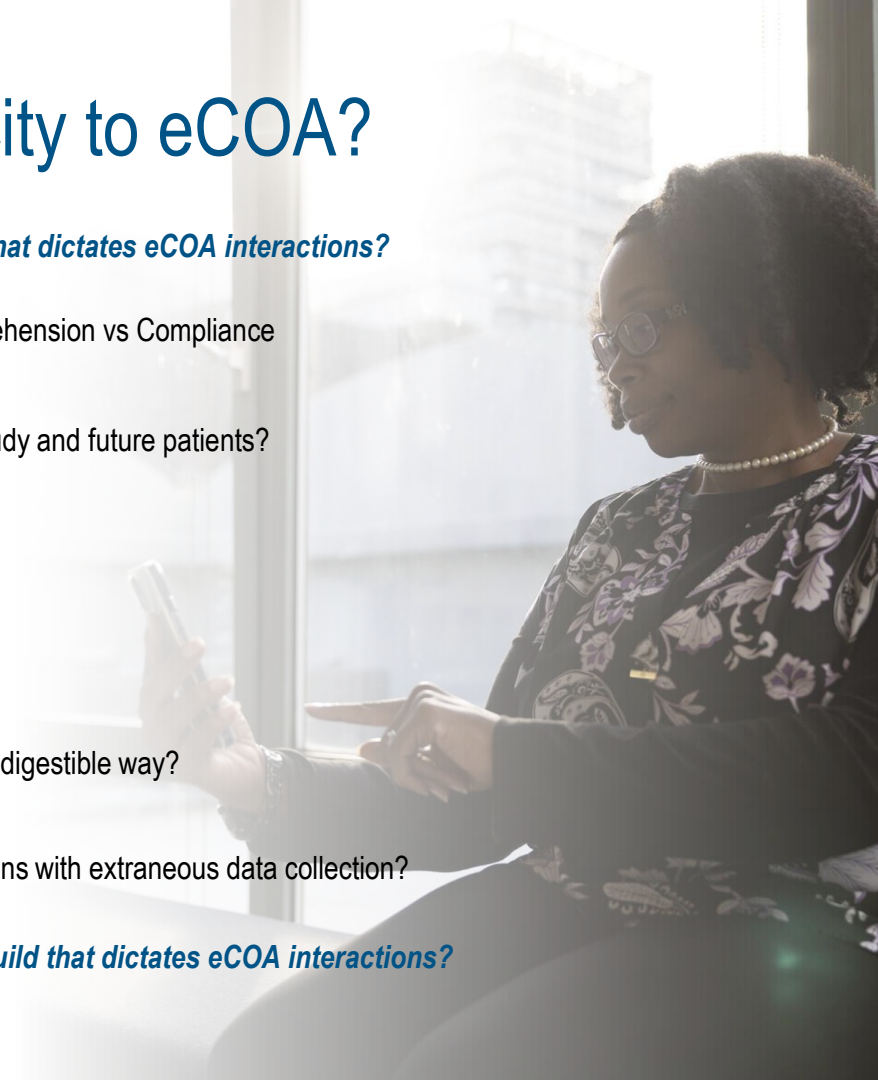


# How do we bring patient centricity to eCOA?

***Have you thought about the end users when designing a protocol/build that dictates eCOA interactions?***

- Will your patients understand what they are being asked to do? Comprehension vs Compliance
- Do participants understand why their responses are important to the study and future patients?
- Have you made participation as least burdensome as possible?
- Are you asking the right questions to get answers that power insight?
- Is what the patient reads and responds to being presented to them in a digestible way?
- Does the build capture the essentials without overburdening participations with extraneous data collection?

***HOW have you thought about the end users when designing a protocol/build that dictates eCOA interactions?***





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# Ease of Use

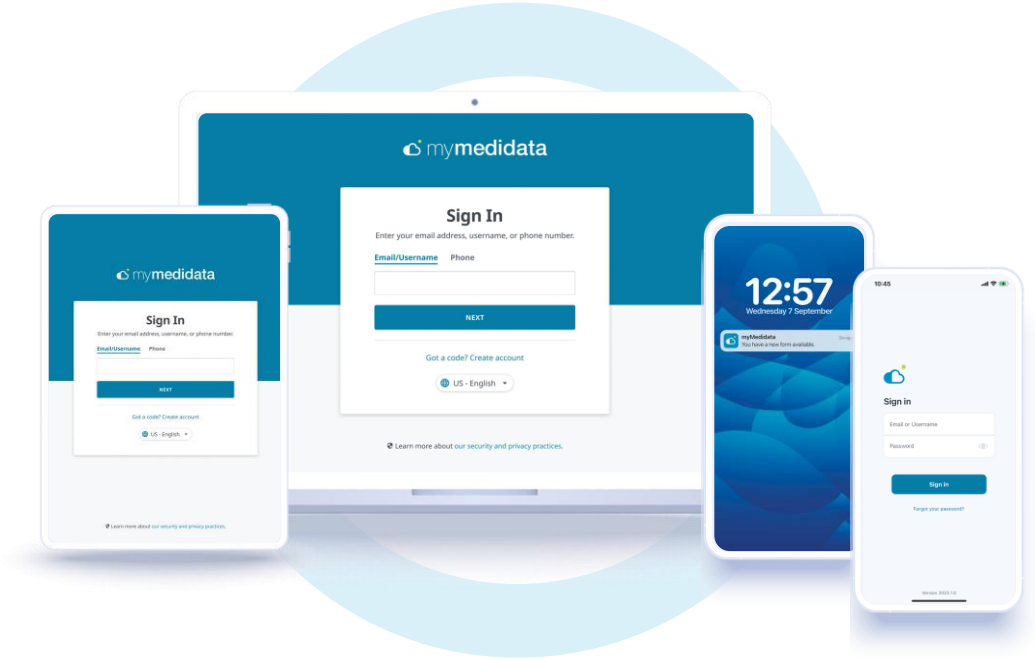
*Patients wanted a simple, centralised experience where they could access all their study activities and information*

myMedidata serves as a patient portal, which surfaces the most relevant information or task

# Meeting the Patient Where They're At

*Patient's wanted to be able to access study tasks from any device*

We created a unified iOS, Android and web browser version of myMedidata

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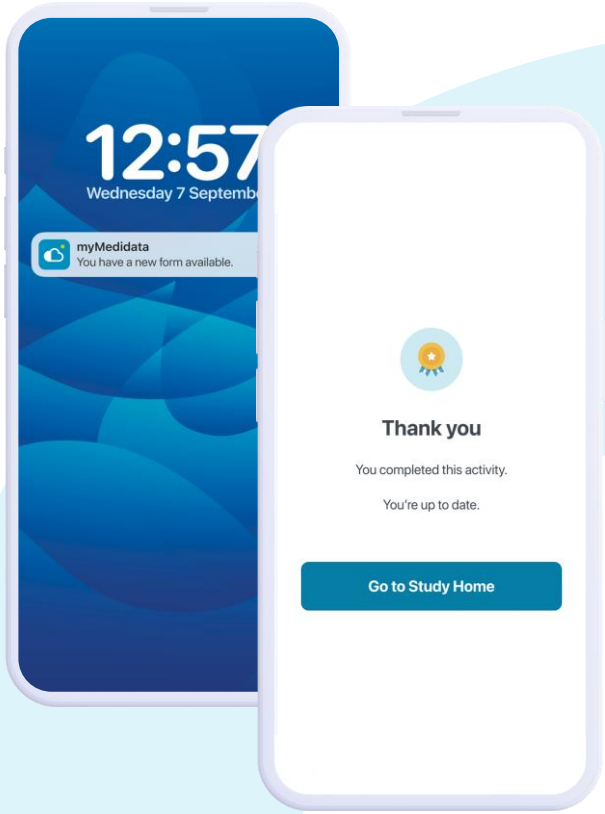
# Avoid “Gamification”

*Patient’s felt certain design elements were inappropriate for the context of a clinical trial*

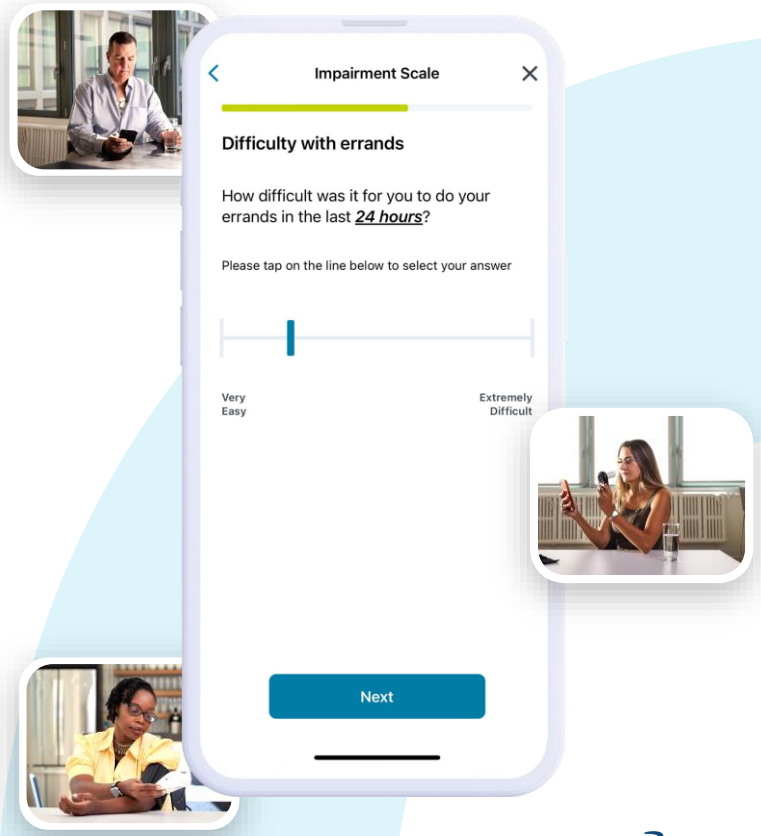
We significantly simplified elements of patients engagement



# Just-in-Time Data Capture

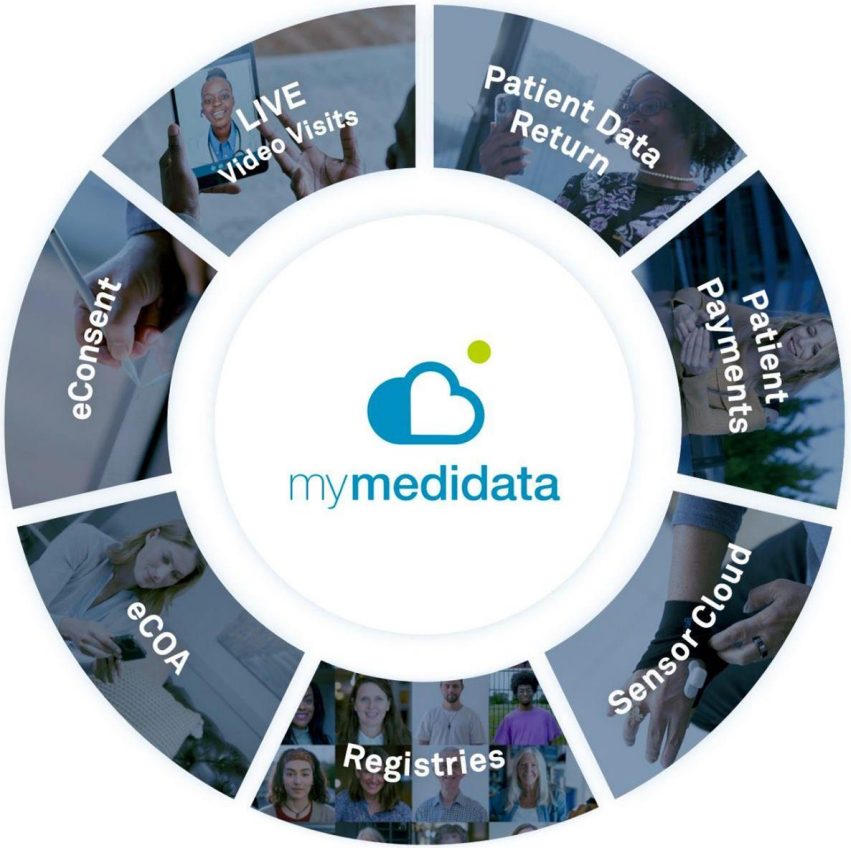
*Patient's found the volume of information they were asked to provide, particularly during onboarding, was overwhelming*

We implemented design patterns that ask for relevant information just before it is actually needed



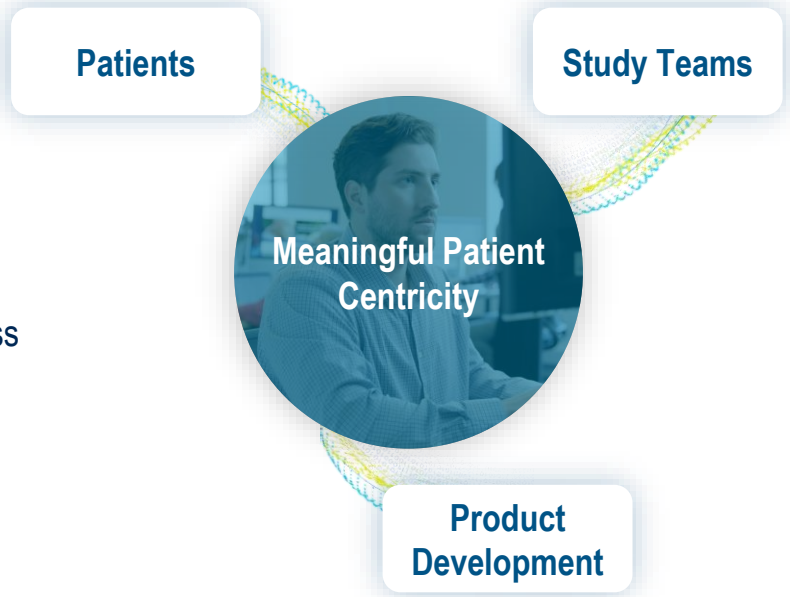
# The patient Journey

## built on the foundation of eCOA!



# Summary

- Trials *are* patients - without their engagement we don't have data
- Patients want to use technology in the context of clinical research
- Patient insights have to be intentionally baked into the development process
- What is asked for is often strikingly simple




IF WE
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