

# Innovative thinking for increasing participants diversity and inclusion in clinical trials.

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DACH Conference - Stream B: Innovation & Technology – 29 Oct 2024

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- Statements made in this talk are those of the individual presenter and, unless expressly stated to the contrary, they are not necessarily the position of Pfizer.

# Outline

## Innovative thinking for increasing patient diversity and inclusion in clinical trials

- Increasing diversity in clinical trial patient recruitment
- Understanding why diversity in clinical trials is important for trial outcomes
- Exploring how to advance medicine through increased diversity

# The motto

- Clinical trials play a fundamental role in medical research
- Participants Safety + Data Quality ensure meeting expected outcomes/objectives
- Public health Value & Meaning of the outcome ! >>> Diversity and Inclusion



<https://tsergas.ca/blog/diversity/shifting-from-diversity-and-inclusion-to-diversity-equity-and-inclusion/>

# Diversity & Inclusion in clinical trials

## Diversity

- Wide range of differences
- Gender, Race, Age, Sexual orientation, Religious values, Social class, ...

## Inclusion

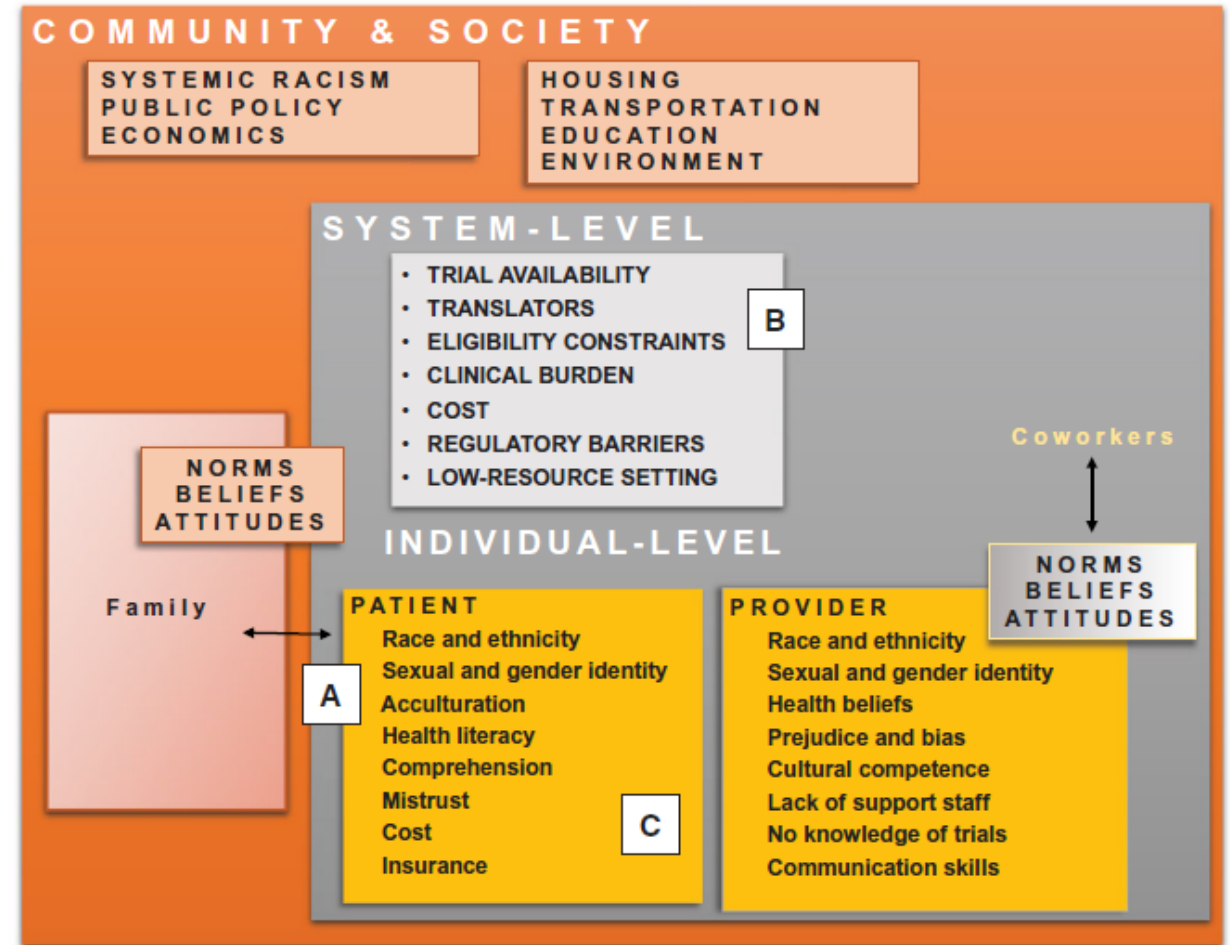
- Means to include everyone in a diverse group
- Supporting their differences so they can freely participate



<https://tsergas.ca/blog/diversity/shifting-from-diversity-and-inclusion-to-diversity-equity-and-inclusion/>

# Diversity & Inclusion in clinical trials: issues

- High priority topic in the last decade
- Historically low CTE from some communities or background (women, elderly, ethnicity)
- e.g. cancer trials
  - Overall cancer CTE in US: 8%
  - Cancer CTE of BIPOC : 15%
  - BIPOC in USA population: 40%
- Compromised generalizability of outcomes, miscalculation DFS rates, erroneous estimates of treatment efficacy => more health disparities



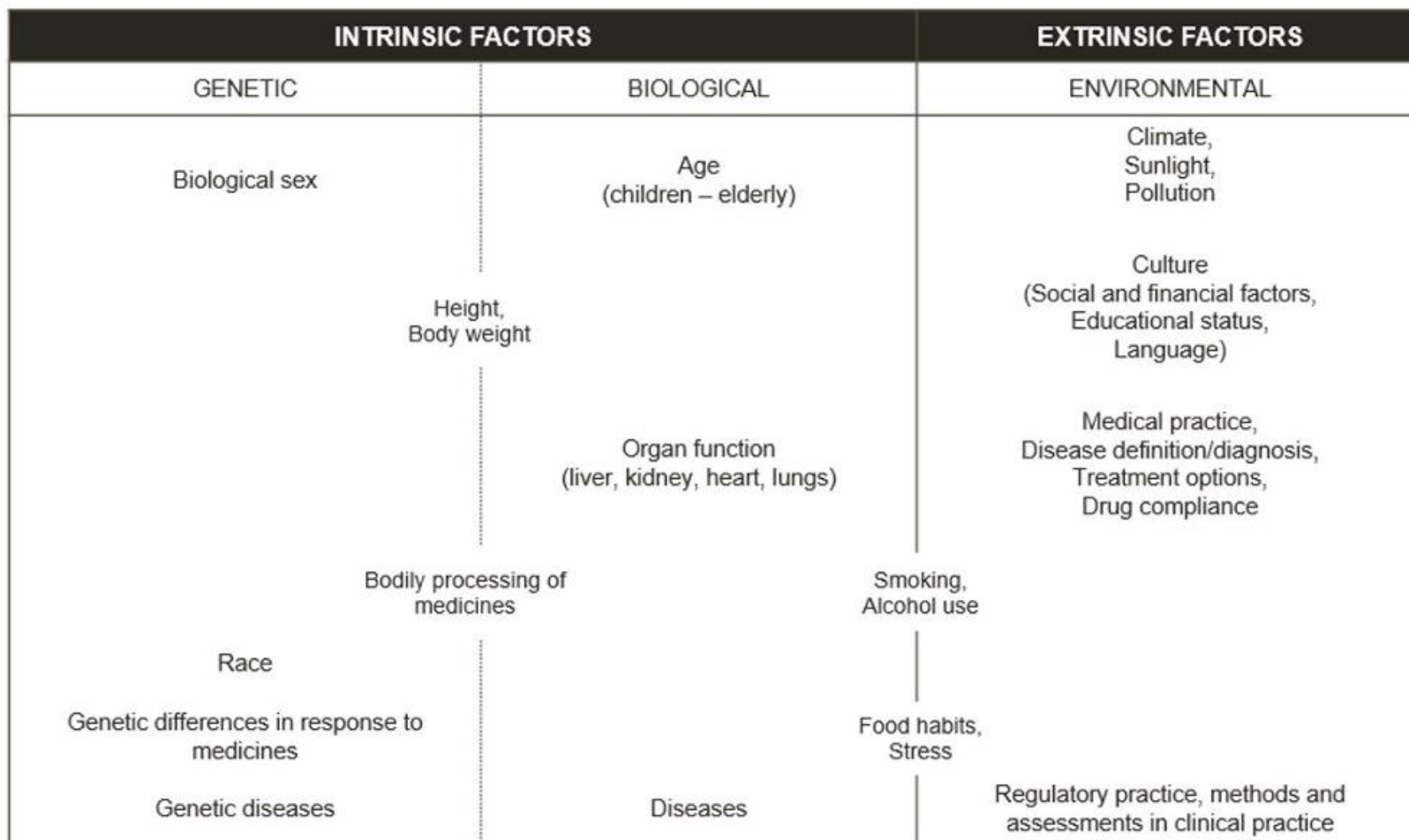
CTE: Clinical Trial Enrollment  
BIPOC: Black, Indigenous, and People of Color  
DFS: Disease Free Survival

Khan et al. Cancer. 2022

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Khan et al. Cancer. 2022

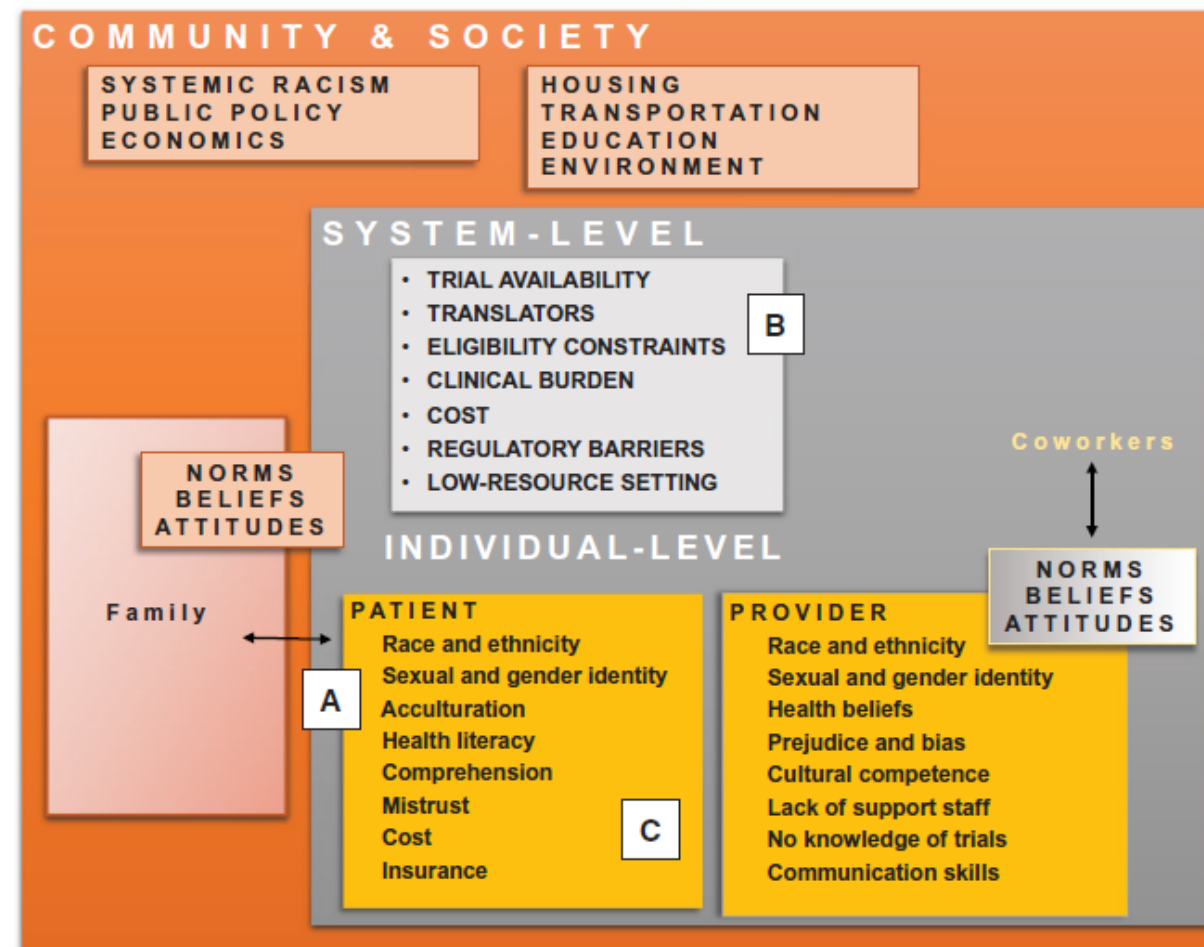
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# Diversity & Inclusion in clinical trials: targeting issues



Need for a **systematic approach** to  
target **D&I related issues** in clinical trials enrollment



Khan et al. Cancer. 2022



# Diversity & Inclusion in clinical trials: FDA guidance

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## Enhancing the Diversity of Clinical Trial Populations — Eligibility Criteria, Enrollment Practices, and Trial Designs Guidance for Industry

U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Drug Evaluation and Research (CDER)  
Center for Biologics Evaluation and Research (CBER)

November 2020  
Clinical/Medical

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<https://www.fda.gov/media/127712/download>

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## Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials Guidance for Industry

### *DRAFT GUIDANCE*

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to <https://www.regulations.gov>. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact (OCE/CDER) Lola Fashoyin-Aje, 240-402-0205, (CBER) Office of Communication, Outreach, and Development, 800-835-4709, or 240-402-8010, or [CDRHClinicalEvidence@fda.hhs.gov](mailto:CDRHClinicalEvidence@fda.hhs.gov).

U.S. Department of Health and Human Services  
Food and Drug Administration  
Oncology Center of Excellence (OCE)  
Center for Drug Evaluation and Research (CDER)  
Center for Biologics Evaluation and Research (CBER)  
Center for Devices and Radiological Health (CDRH)  
Office of Minority Health and Health Equity (OMHHE)

April 2022  
Clinical/Medical

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<https://www.fda.gov/media/157635/download>

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## Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies Guidance for Industry

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Office of Minority Health and Health Equity (OMHHE)  
Office of Women's Health (OWH)

June 2024  
Clinical/Medical

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<https://www.fda.gov/media/179593/download>

# Diversity & Inclusion in clinical trials: DAP

## Determine enrolment goals

- **Race** : as per guidance for reporting race
- **Ethnicity** : as per guidance for reporting ethnicity
- **Sex** : as per guidance for reporting sex
- **Age group** : list for clinically relevant age subsets

## Rationale for enrolment goals

- Include sufficient information and analysis to explain how enrollment goals were determined

## Measures to meet enrolment goals

- Description of enrollment and retention strategies for defined population subsets
- Description of monitoring plan to ensure goals are met

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# Diversity & Inclusion in clinical trials: EMA guidance

No true equivalent of  
FDA guidance on Diversity  
and Inclusion in Clinical trials

ICH guideline E8 (R1) on general  
considerations for clinical studies

1 December 2022

EMA/CHMP/ICH/544570/1998 Corr\*

Regulation (EU) No 536/2014 of the  
European Parliament and of the Council of

16 April 2014

on clinical trials on medicinal products for human  
use, and repealing Directive 2001/20/EC

*Pregnant women*

*Lactating women*

*Children (ICH E11)*

*Elderly (ICH E7)*

*“Unless otherwise justified in the protocol, the  
subjects participating in a clinical trial should  
represent the population groups,  
for example gender and age groups, that are  
likely to use the medicinal product  
investigated in the clinical trial”*

# Diversity & Inclusion in clinical trials: “let’s increase it”

1

E6(R3)

## II. Principles of ICH GCP

1.4 When designing a clinical trial, the scientific goal and purpose should be carefully considered so as not to unnecessarily exclude particular participant populations. The participant selection process should be representative of the anticipated population who is likely to use the medicinal product in future clinical practice to allow for generalising the results across the broader population. Certain trials (e.g., early phase, proof of concept trials, bioequivalence studies) may not require a heterogeneous population.

Ensuring inclusive participation, access,  
and diverse representation in clinical trials

is not only a matter of equity,

**it’s good science –**

leading to the development of  
more options to treat and prevent diseases  
for as many people as possible.

# Diversity & Inclusion in clinical trials: “let’s increase it”

Intention to achieve  
representativeness:  
DAP

Foundation of trust  
(participant &  
community)

Address barriers to  
CTE: no more one  
size fits all

Flexible approach to  
recruitment and data  
collection

Networking with  
relevant community  
stakeholders

Address professional  
scientific, societal  
expectation

Study team  
optimized and  
aligned to goals

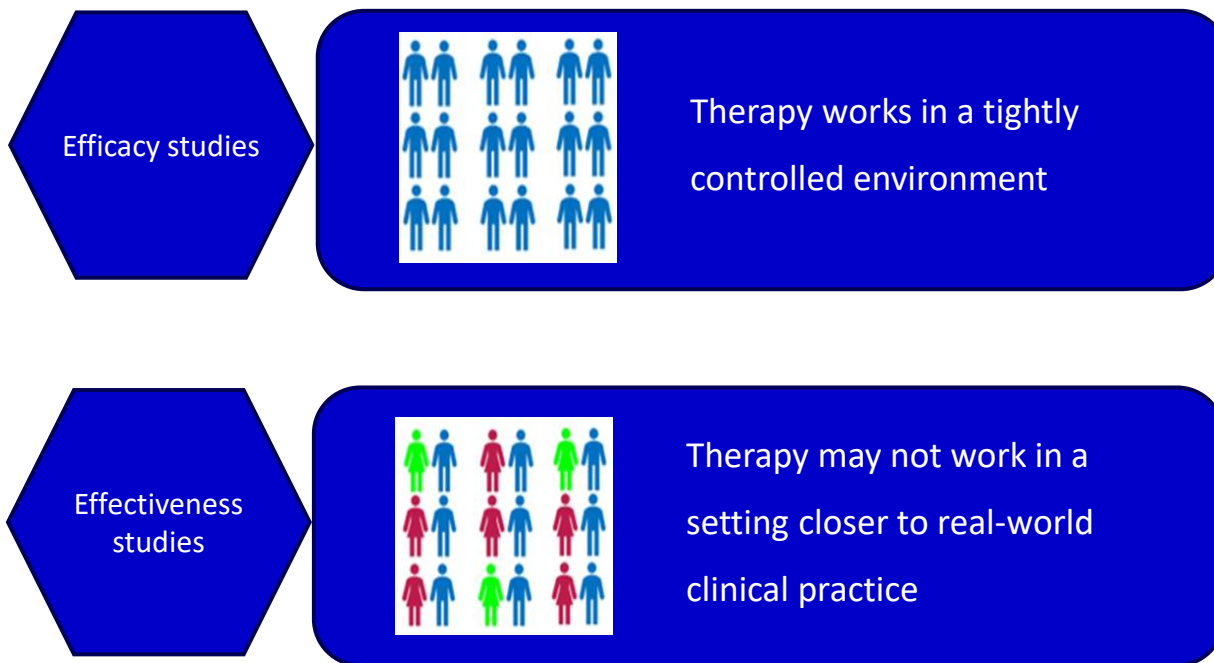
Time and budget  
investments to  
support goals

# Outline

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# Importance of Diversity & Inclusion



- Evaluation of clinical trials 1997-2014 across 29 countries: 86% of trial participants identified as White.
- US study of 1.9M adults over 55Y: Black patients were 54% more likely to develop dementia over 10Y period
- Yet, 83 clinical trials of drugs for AD over the last 10Y included only 2% Black

Versavel et al., Contemporary Clinical Trials 2023



# Importance of Diversity & Inclusion

## Response to antidepressants



Tricyclic antidepressant



Serotonin reuptake inhibitors

Baca et al., Progress in Neuro-Psychopharmacol and Biological Psychiatry 2004  
Bano et al., Journal of College Physicians and Surgeons Pakistan 2004  
Kornstein et al., American Journal of Psychiatry 2000

## Response to Warfarin

- Prevention of deadly thromboembolisms (heart, lung, brain)
- Preventing clots => Risk bleeding
- 20-fold interpatient variability in dose requirements (African vs Asian vs European ancestries)
- Variability linked to genetic variants CYP2C9 (metabolism) and VKORC1 (receptor)
- MA in 1951, but recognition genotype-guided dosing only in 2013: early trials participants were predominantly of European ancestry

Drozda et al., Pharmacogenet Genomics 2015

# Importance of Diversity & Inclusion

## *Fail to prepare, prepare to fail*

- Generalization of CT results to larger/whole population is compromised
- Higher costs to manage consequences of “further increased” health disparities
- Hindering innovation by missing greater variation of overall effectiveness at early stage of development
- Limited access to effective medicine as MA trends towards considering participants’ background
- Undermine trust of clinical research enterprise

(e.g. lack of pregnant women in SARS-CoV-2 vaccine trials)

NAS & NIH, 2022, doi: <https://doi.org/10.17226/26479>

# Outline



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# PCRU experience over 30 years

## Context

- Pfizer Clinical Research Unit
- Experience shared is limited to Phase 1 trials with healthy volunteers
- Aspects can be transposed to other phases of clinical trials

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## Diversity in Our Clinical Trials

Race, ethnicity, age, and sex can all impact how different people respond to the same medicine or vaccine. This is why diversity among clinical trial participants is so important. The more diverse a group of clinical trial participants is, the more we can learn about the safety and efficacy of a potential medicine or vaccine for people now and in the future.

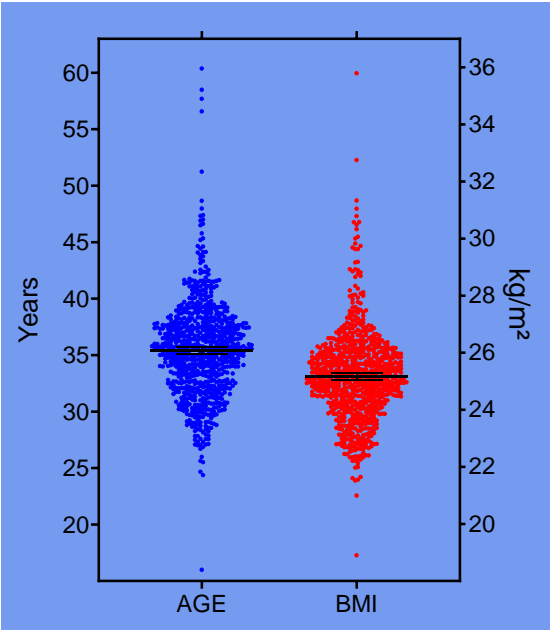
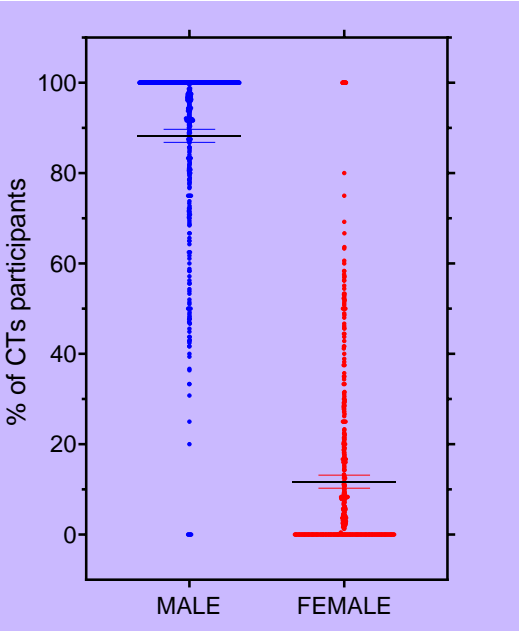
# PCRU experience over 30 years

## Subset participants in 781 CTs

	N / Mean	%
Randomized	21492	
Individuals	6097	
Males in CT	18864	87.77
Females in CT	2607	12.13
M/F ratio	7.24	
White	10153	47.24
Black	5101	23.73
Asian	4463	20.76
Others	1700	7.91
Age	35.21	
Weight	77.08	
Height	174.67	
BMI	25.20	

Global PCRU : 781 Phase 1 clinical trials involving 6097 individual healthy participants (M/F 7.24), who were included in 21492 randomization events.

The “average” PCRU study participant is a 35Y old White male, measuring 174 cm for 77 Kg, and presenting a suboptimal BMI of 25.16 Kg/m<sup>2</sup>.



# PCRU experience over 30 years

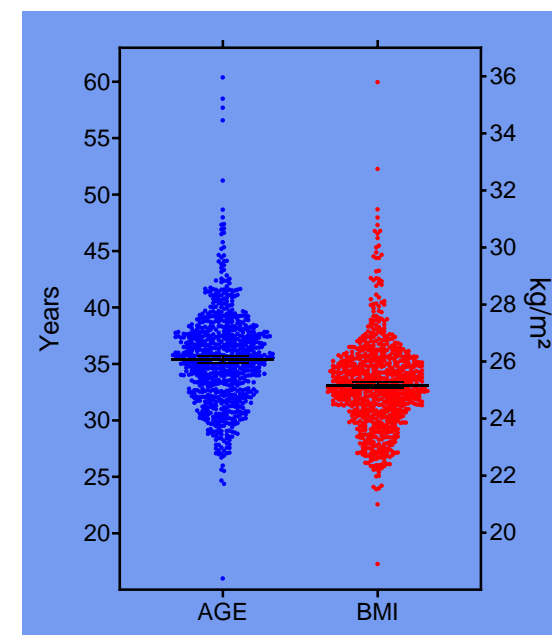
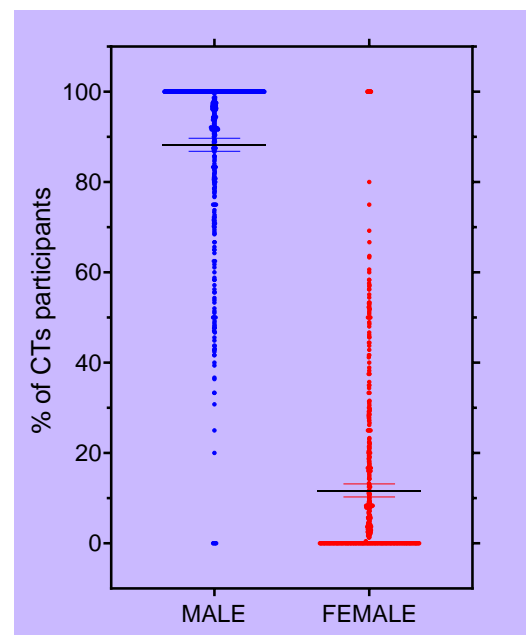
## Some considerations

### Low Female representation

(M/F ratio 7.24; no Gender split in protocols)

Age groups < 25 and > 45 years under-represented

Low and High range BMI are under-represented





# PCRU experience over 30 years

## Perspectives addressing increased D&I

*Campaign targeting females, systematically invite to CT subscription (no logistics blockade)*

*Expand protocol upper range: 18 years old and above or 18 to 65 years old vs 18 to 55 years old.*

*Expand protocol-defined range to 16-32 kg/m<sup>2</sup> vs 18-30.5 kg/m<sup>2</sup>*

*Clariness, Medians, Website, Social Media, Word of mouth (Ambassador program)*

**Give the best of yourself**  
by participating in a clinical study

**Goal**  
→ Determine the concentration of a medication in breast milk.

**Profile**  
→ You are a healthy woman aged between 18 and 45  
→ You gave birth at least 12 weeks ago  
→ You are breastfeeding your baby and agree to temporarily interrupt (4 - 5 days)

**We offer**  
→ A financial compensation for your participation and your travel costs

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# PCRU experience over 30 years

## Recent innovative activities

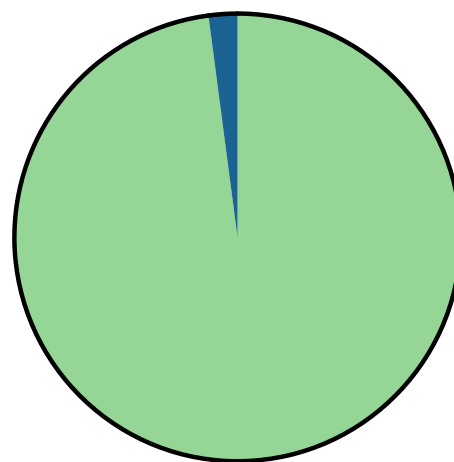
*Return trials results to participants (pre-dose data shared upon request)*

*Self-subscription via Charlie chat bot – Updated Fees for Flight, Accommodation, Contraception*

*Participants Survey prior to launching Decentralized Clinical Trial*

*Participant-centric approach (Satisfaction survey, Shanna Horowitz)*

a. Overall Satisfaction

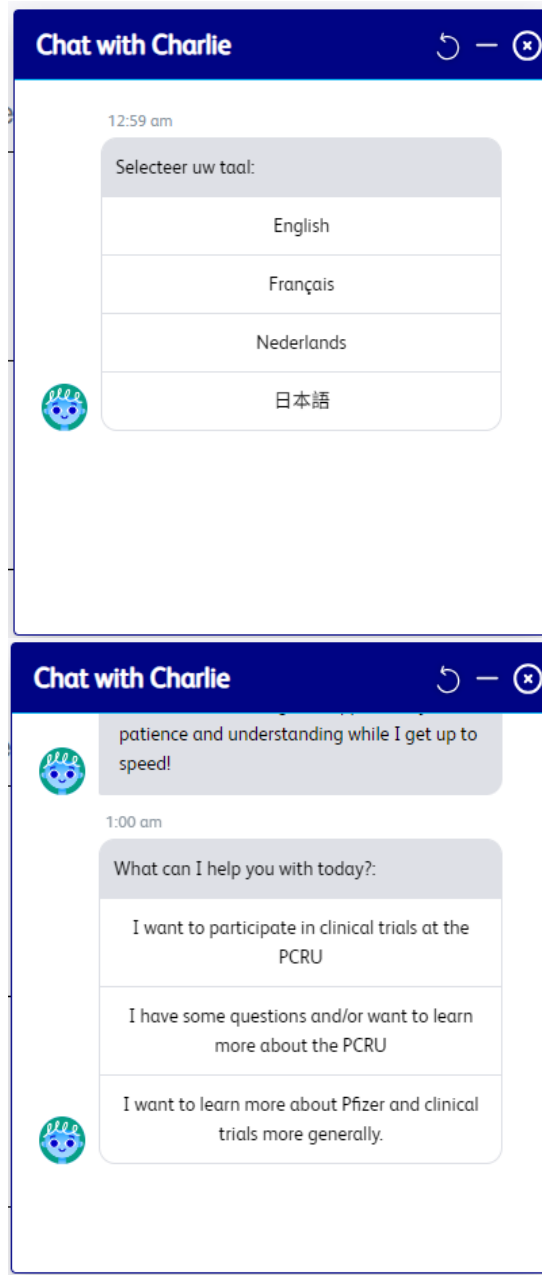


97.92% Yes

2.08% No

Total = 144

3/144 participants  
wouldn't return for a trial



# PCRU experience over 30 years

## Recent innovative activities

Participant-centric approach (Shanna Horowitz)

Telemedicine


Direct to Patient Shipments

Home Nurse


Wearables

e-Consent

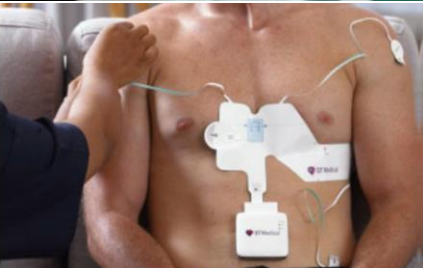
ePRO/eCOA



TASSO  
blood microsampling  
D1-2 / D3-8.

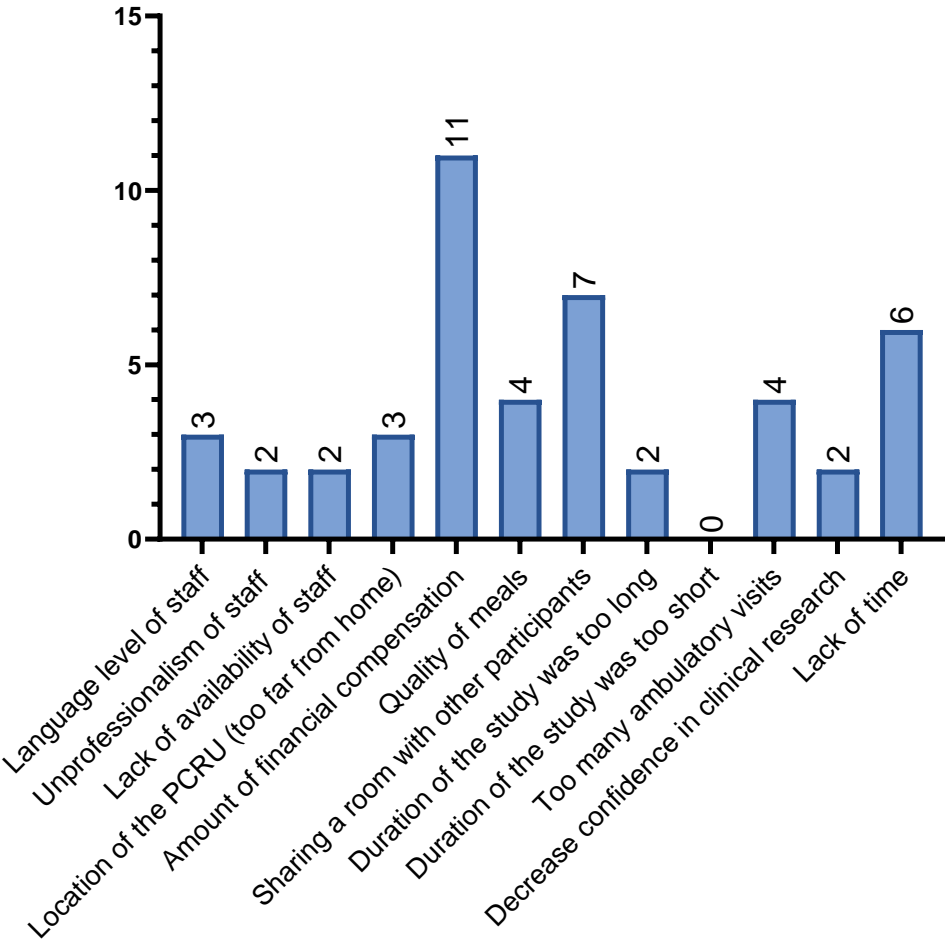


Bio-Beat  
Vital Signs  
D1-2 / D3-5.



PCA 500  
ECG  
D1-2 / D3-5.

c. If NO, for the following reason



# Closing remarks

Clinical trials will continue playing a fundamental role in medical research, but differently

Public health Value & Meaning of CT outcomes are also tied to Diversity and Inclusion

Proactive planning is essential and required to address D&I early in drug development

Ultimately, D&I help ensure that populations who may benefit from innovative interventions are represented in clinical trials



<https://tsergas.ca/blog/diversity/shifting-from-diversity-and-inclusion-to-diversity-equity-and-inclusion/>

# Thank you



**Josué Mfopou Kunjom, MD, PhD**  
Clinical Operations Director



29Oct2024