

How did the healthy volunteer
evolve over the last 10 years?



What is “healthy”

- **WHO:**

*“Health is a state of complete **physical, mental and social** well-being and not merely the absence of disease or infirmity.”*

- **Royal College of Physicians:**

*“An individual who is not known to suffer any significant illness **relevant to the proposed study**, who should be **within the ordinary range** of body measurements”*

- **Textbook of Pharmaceutical Medicine:**

*“An individual who is in good general health, not having any mental or physical disorder **requiring regular or frequent medication**”*



The perfect healthy volunteer


- *In physical, mental and social well-being*
- *Within the ordinary range of body measurements*
- *Absence of illnesses that are relevant to the study i.e.,*
 - *Increase the risk for the participant or,*
 - *Could affect the study results*



Where is the line?

REVIEW

Who is a ‘healthy subject’?—consensus results on pivotal eligibility criteria for clinical trials

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Perspective | Published: 09 April 2014

A need to reconsider the definition of ‘healthy participants’ in epidemiological studies and clinical trials

[G Farhat](#) 

[European Journal of Clinical Nutrition](#) **68**, 724–725 (2014) | [Cite this article](#)

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Evolution of key criteria in the last 10 years

- Comparison of population criteria in phase 1 studies
- 58 phase 1 studies total
 - n=29 from 2014 and n= 29 from 2024
 - Each split equally into FIH and non-FIH
- 3 sources
 - 2 Belgian sites
 - 1 German sponsor





Key Criteria

Age

BMI

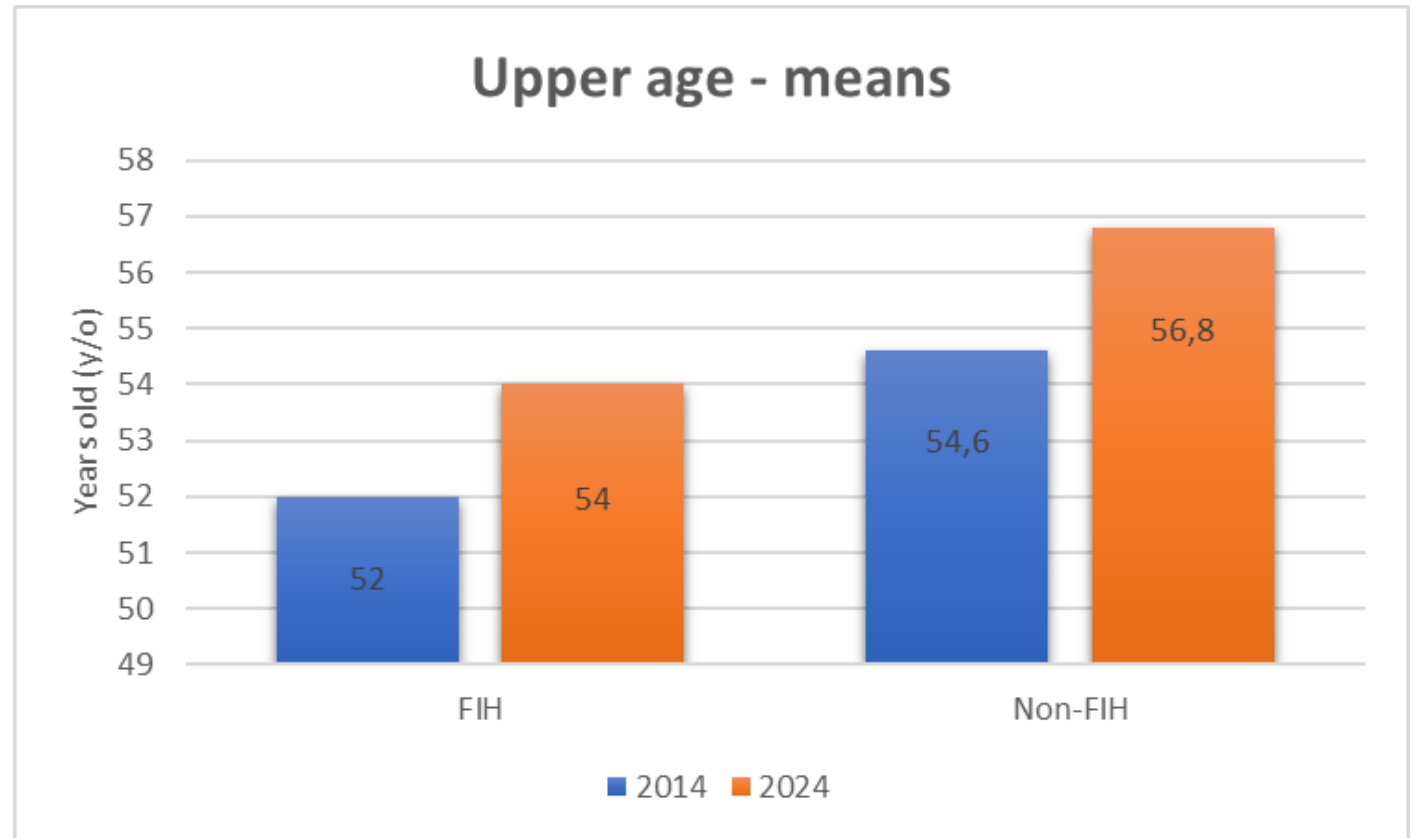
In/exclusion criteria

Medical parameters

Gender

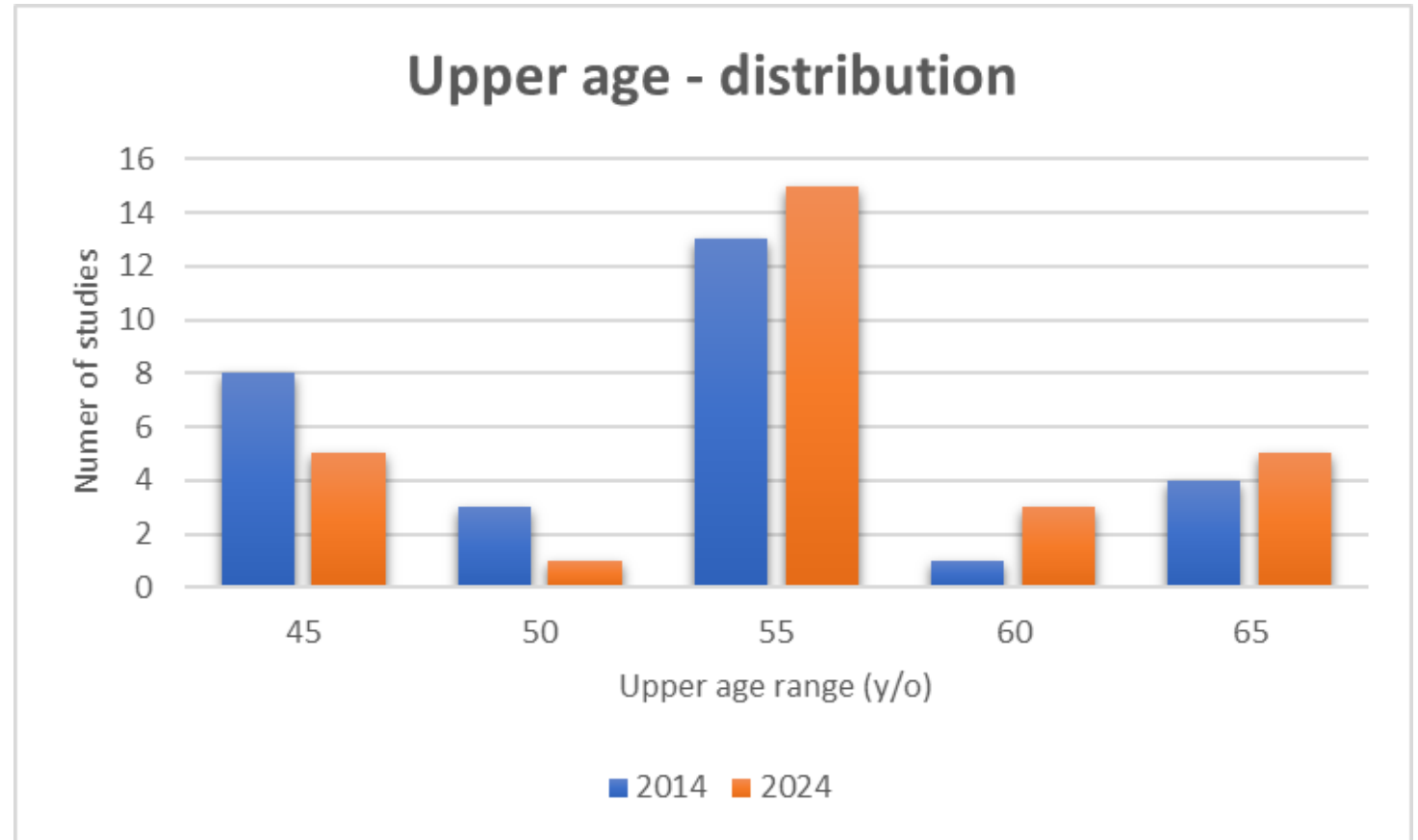
Age

- Slight increase of ~4%



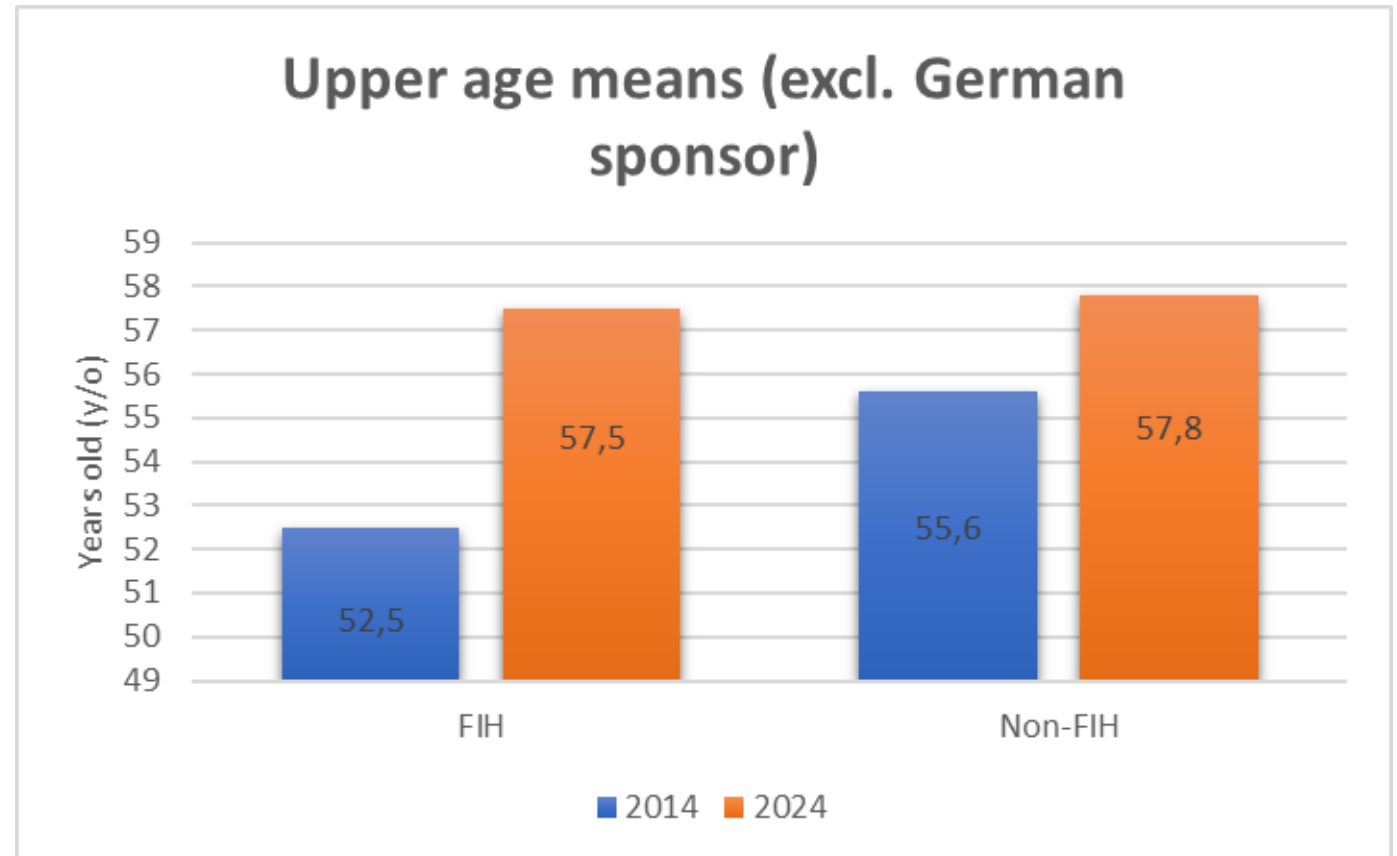
Age

- 50% of studies up to 55 y/o
- 2014 to 2024: overall age shift from 45-55 to 55-65 y/o



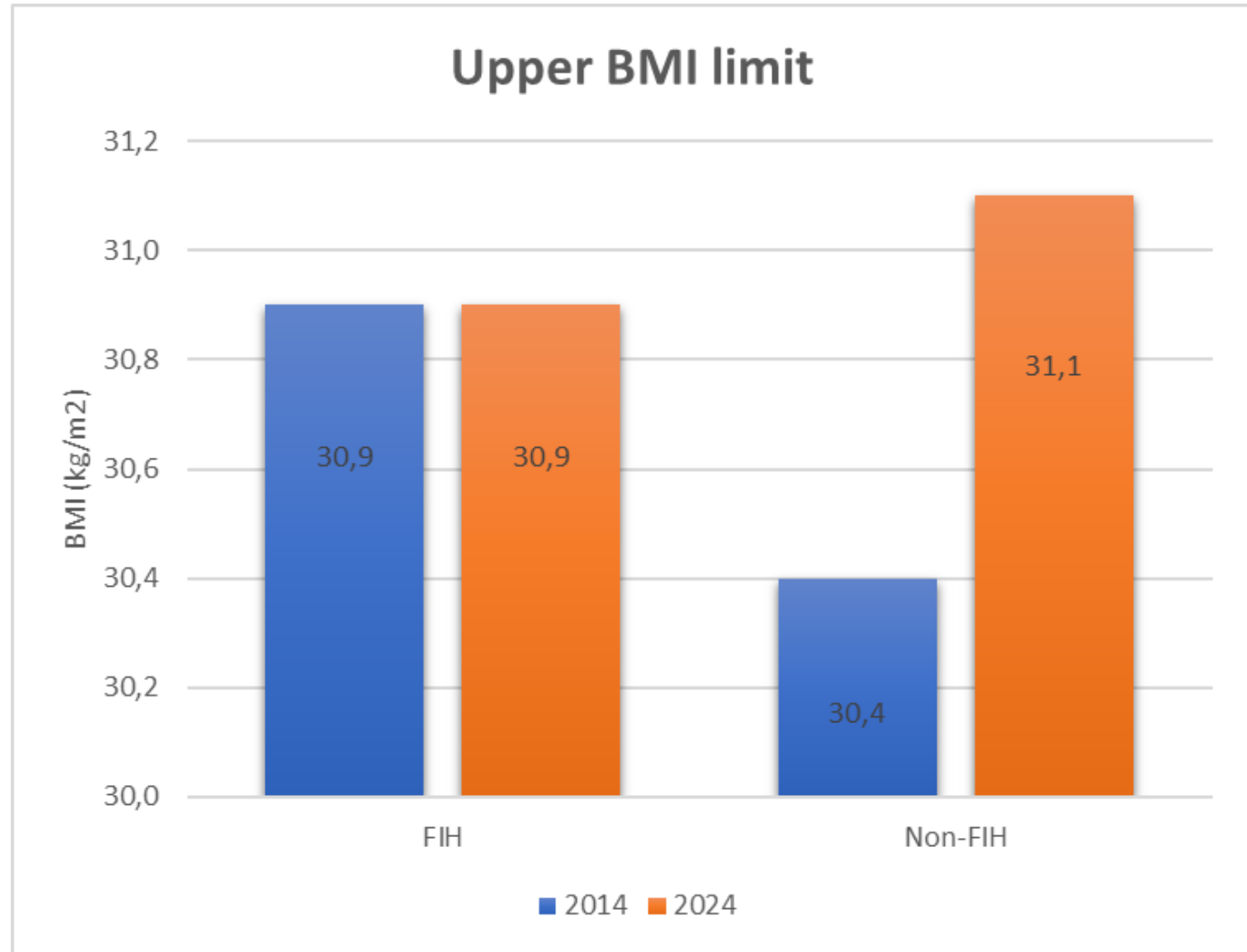
Age

- If focusing only on Belgian sites
 - Broader diversity in sponsor nationalities
- More pronounced increase
 - FIH: ~10% ↑



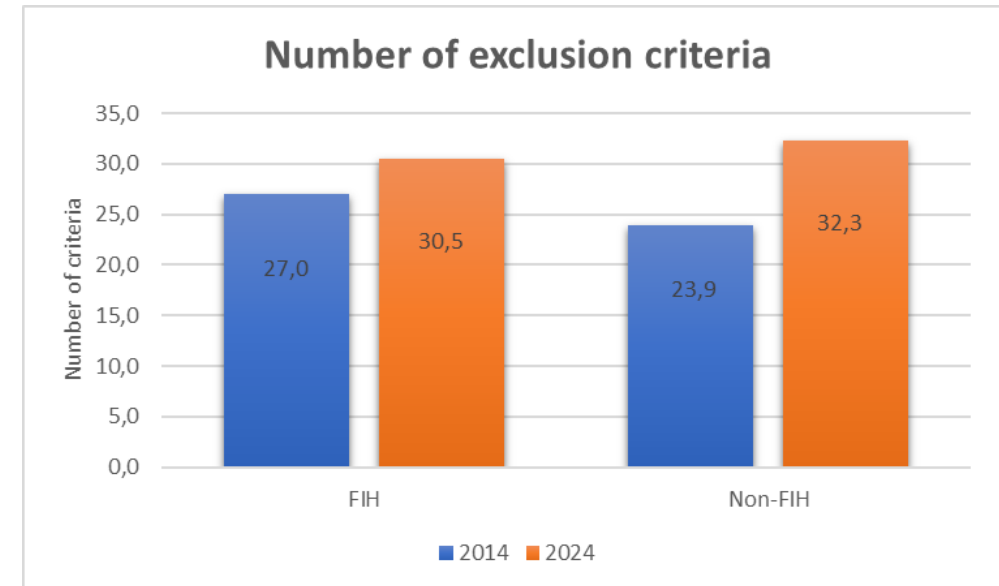
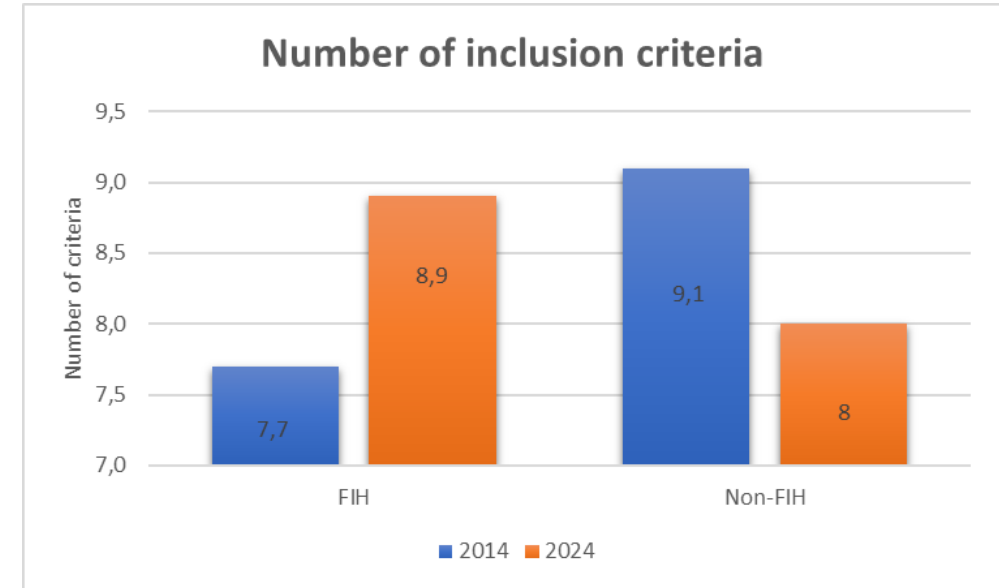
BMI

- No change in FIH
- Slight increase in non-FIH



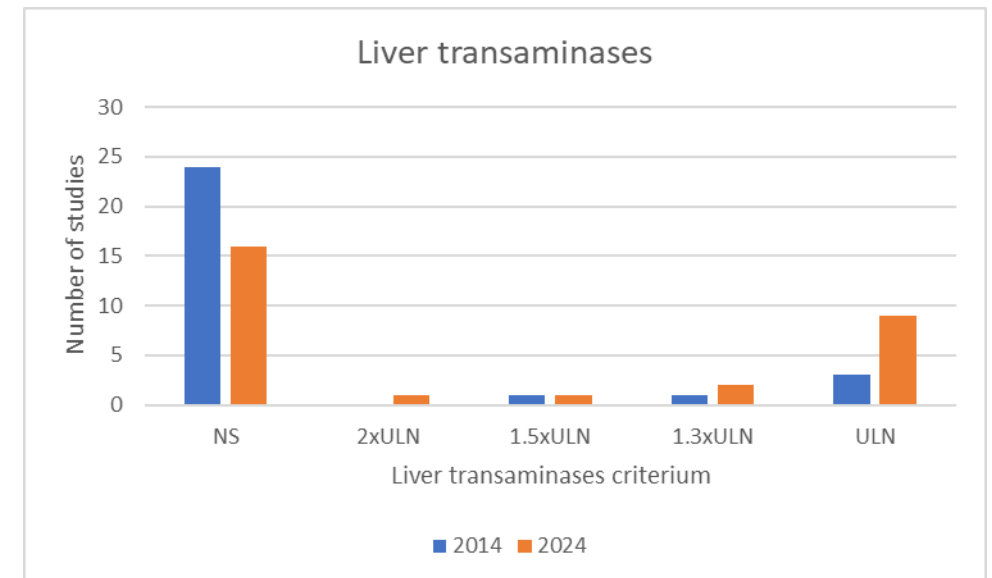
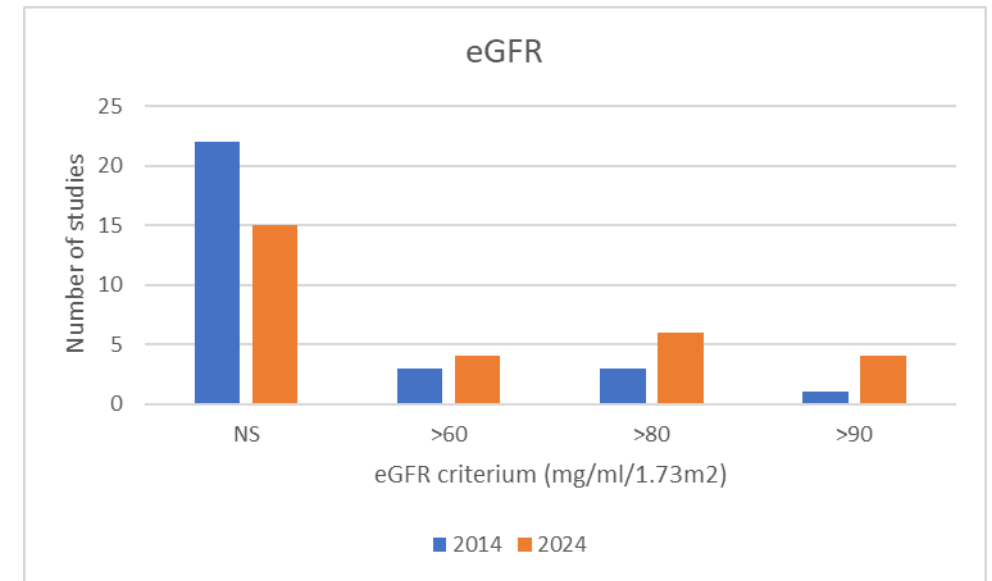
In/exclusion criteria

- No apparent change in inclusion criteria
- Only slight increase in exclusion criteria in non-FIH
- Overall no significant changes despite perceived increase in complexity in clinical trials



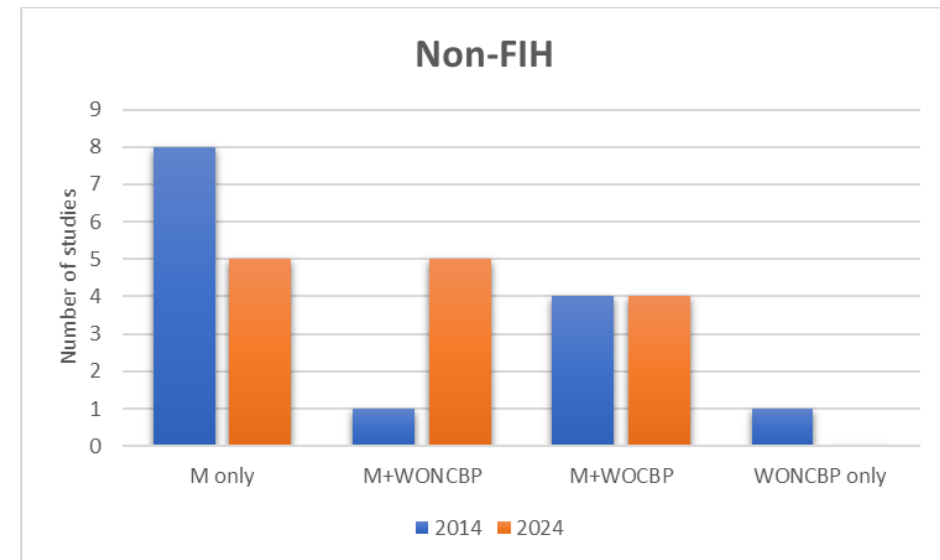
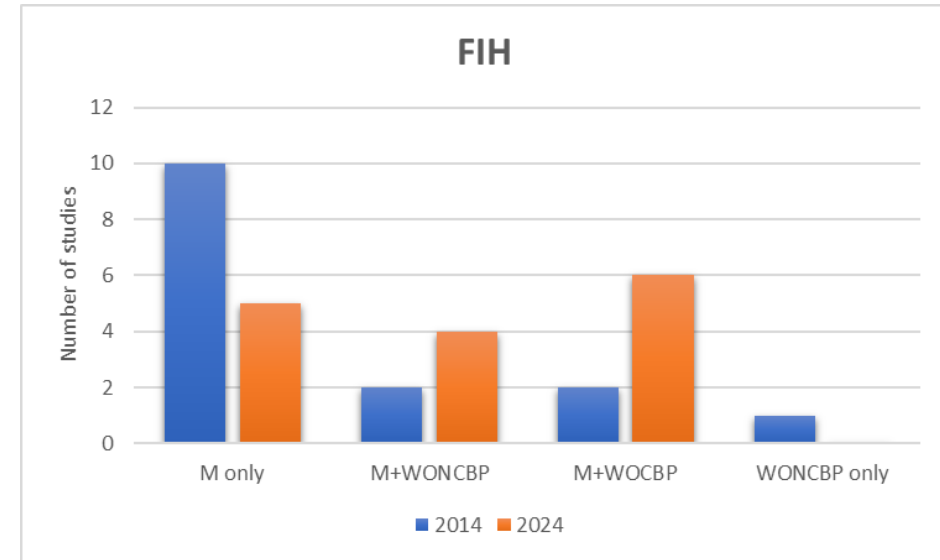
Medical parameters

- Vital signs
 - No significant differences over the past 10 years:
 - Blood pressure
 - SBP 90 – 140 mmHg
 - DBP 50 – 90 mmHg
 - HR 45/50 – 90/100 BPM
- ECG
 - No significant differences over the past 10 years:
 - QTcF 450 ms
 - QRS 120 ms
 - PR 200 - 220 ms
- Labs
 - More specified and stringent criteria for:
 - eGFR
 - Liver transaminases
 - Applies to both FIH and non-FIH



Gender

- Significant decrease in “male-only” FIH and non-FIH studies
- Trend for increase in WONCBP and WOCBP inclusion in phase 1 studies



Breakout Session



Explore the boundaries of what is considered healthy



Debate on diversity in phase 1 trials