# The Neuroscience Estimand Special Interest Group

Scope, objectives and a look into the future



Marisa Bacchi,<sup>1</sup> Marian Mitroiu,<sup>2</sup> Paul Delmar,<sup>3</sup> Rachid Abbas,<sup>3</sup> Hans Ulrich Burger,<sup>3</sup> Andrew Hartley,<sup>4</sup> Mette Krog Josiassen,<sup>5</sup> Lars Lau Raket,<sup>6</sup> Peter Quarg,<sup>7</sup> Khadija Rantell,<sup>8</sup> Nikolaos Sfikas<sup>7</sup>

<sup>1</sup>Consultant, <sup>2</sup>Biogen, <sup>3</sup>F.Hoffmann-La Roche, <sup>3</sup>MHRA, <sup>4</sup>PPD, <sup>5</sup>H.Lundbeck A/S, <sup>6</sup>Lilly, <sup>7</sup>Novartis

# **Background and Objectives**

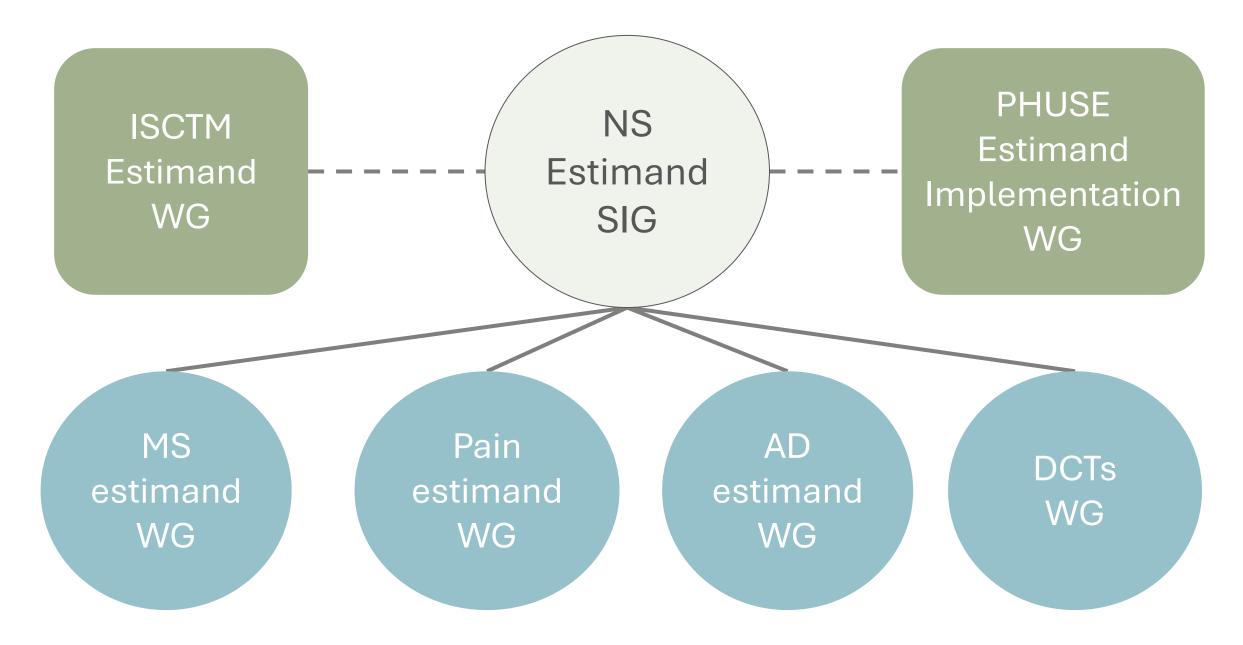
WG was formed around 2016 aiming to connect statisticians working in Neuroscience

Champion
adoption of
ICH E9(R1) in
Neuroscience drug
development

Sharing noncompetitive knowledge and experience

Facilitate industrywide publications Support and share development and adoption of best practices across industry and regulators

### **Neuroscience Estimand Ecosystem**



#### **Recent Activities**

- Parkinson's Disease estimand paper
   [Noci, 2022 doi.org/10.1080/19466315.2022.2116476]
- Migraine estimand manuscript [in preparation]
- Multiple Sclerosis estimand manuscript [in preparation]
- Alzheimer's Disease estimand posters
   and PSI webcast [https://psiweb.org/vod/item/psi-eiwg-webinar-estimands-framework-in-action-the-alzheimer-s-disease-case]
- Estimands in Neuroscience book chapters [submitted]
- Decentralized Trials (DCTs) paper [Burger,
   2023, doi.org/10.1002/bimj.202200370]

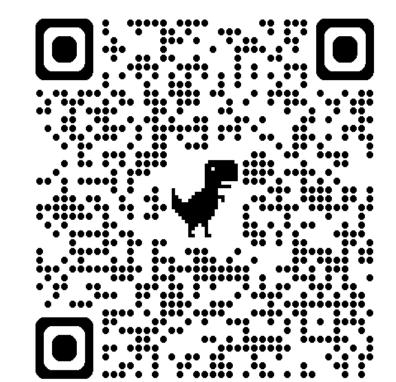
## Looking into the future

- Neuroscience Estimand SIG to continue facilitating better understanding of and driving the implementation of the estimands framework using examples and trial methodology in neuroscience
- Extend membership to more stakeholders, including academia and HTA
- As the estimand framework is becoming commonly employed in drug development, the Neuroscience Estimand SIG aims to continue driving the implementation with examples and trial methodology in neuroscience and continues connecting people working in Neuroscience
- We are exploring new topics, including digital endpoints, study designs, and the use of Al.

## Interested in joining?

# We want to hear from you!





Contact: paul.delmar@roche.com