



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Commentary on the session on Alzheimer's disease

Concepts of interest and outcome measurement tools at different stages of development

2022 ISCTM Autumn conference

Presented by Lorenzo Guizzaro on 8 September 2022

An agency of the European Union





Disclaimer

The views expressed in this presentation and in the following panel discussion are the personal opinion of the author and should not be understood as being made on behalf of or reflecting the position of the EMA or one of its committees or working parties.



What to demonstrate

Effect on Cognition

Effect on daily functioning

Clinical meaningfulness of the effect

How to demonstrate it

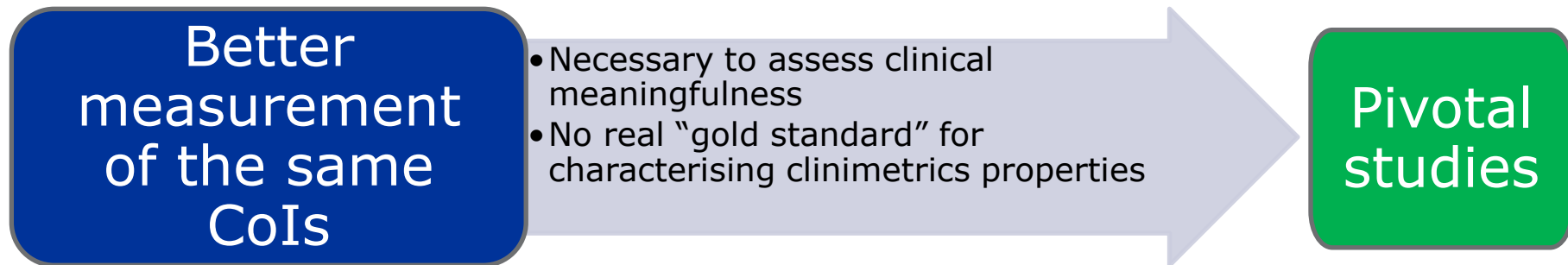
Limitations of available methods are acknowledged

Development of more sensitive tools are encouraged

Studying cognition and function with one tool is possible

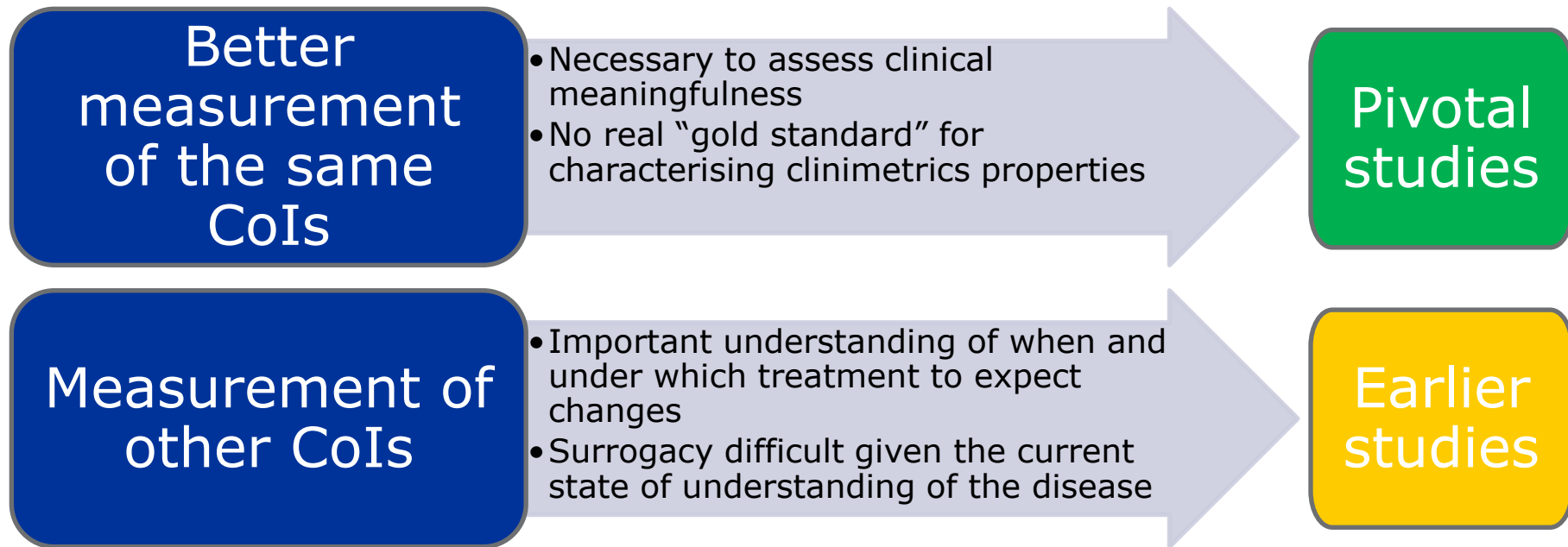


Opportunities for innovation in outcome measurement





Opportunities for innovation in outcome measurement





EMA and the development of outcome measurement tools



Initial
orientation

Innovation Task

Force, forum for early dialogue, informal scientific brainstorming, and , orientation towards the next formal steps.



EMA and the development of outcome measurement tools

Initial
orientation

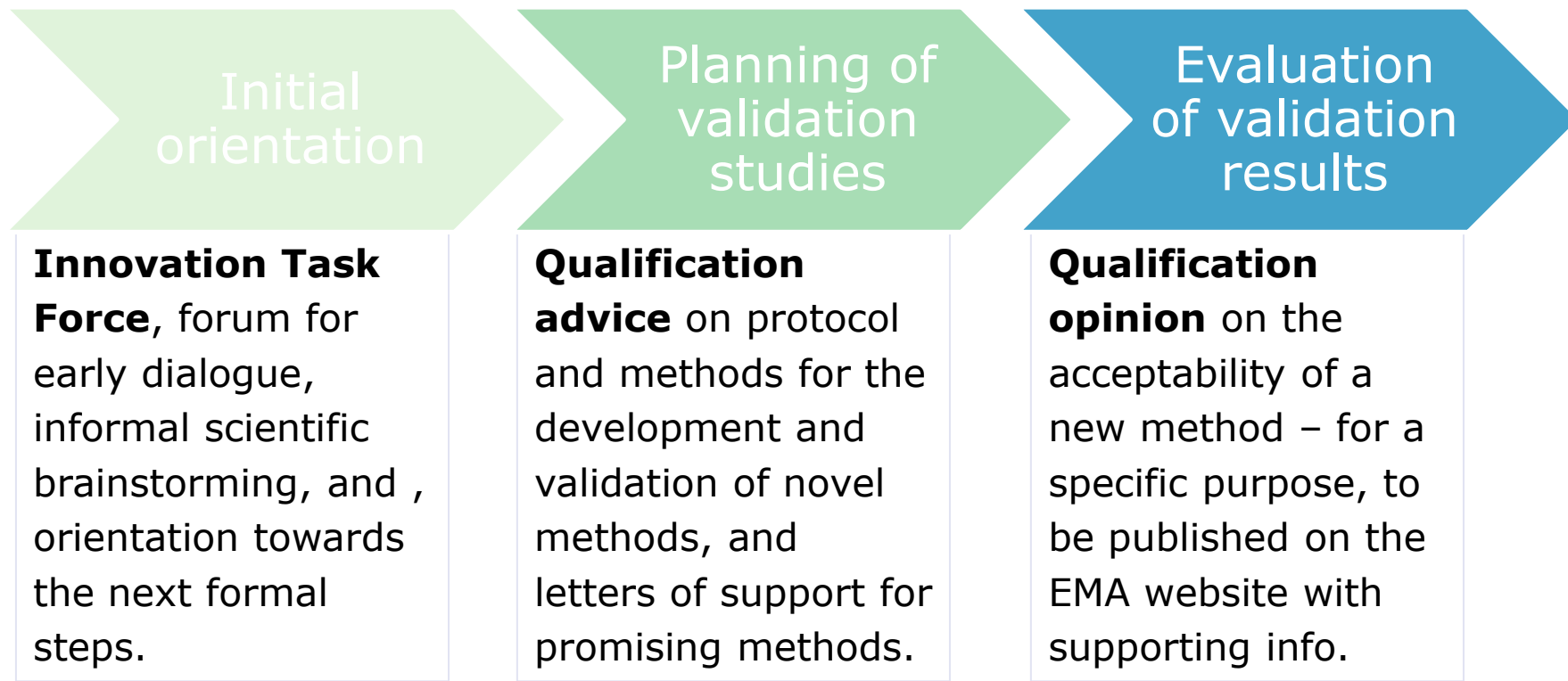
Innovation Task Force, forum for early dialogue, informal scientific brainstorming, and orientation towards the next formal steps.

Planning of
validation
studies

Qualification advice on protocol and methods for the development and validation of novel methods, and letters of support for promising methods.



EMA and the development of outcome measurement tools





Any questions?

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Telephone +31 (0)88 781 6000

Send us a question Go to www.ema.europa.eu/contact

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