Estimands in Oncology Working Group

Tuesday, 14th June 2022, PSI



Status of the Working Group

As of 30 March 2022, the working group

- has 85 members representing 43 companies / institutions,
- regularly interacts with eight Health Authorities globally,
- regularly organizes sessions and presents at conferences,
- has started to interact with academic colleagues,
- currently operates in 10 agile task forces.

Regularly updated list of Publications and Events with contributions from the working group are available on www.oncoestimand.org.



Task Forces

Principal Patient-Quantification **Estimands** Duration of stratification in reported engagement of follow-up responses clinical trials outcomes Prognostic or Early Conditional Real-world data predictive development Estimands for vs. marginal and estimands biomarker estimand Safety effects nexus (EDEN) subgroups

Member rosters of these task forces are available at www.oncoestimand.org.



Estimand Adoption

Stefan Englert

Tuesday, 14th June 2022, PSI



Timeline

Guideline Adoption

> Industry Adoption

Guideline Development

2012

2014

Adoption of E9(R1) Public Concept Paper consultation •October 2014 •August 2017 Final Concept Paper •November 2015

2016

E9(R1) End of consultation

2018

Founding of

Working

February

Group

2018

2020

2022

FDA/EMA **EMA Adoption** FDA Adoption Guidances •January 2020 •May 2021

EMA Effective

•July 2020

Founding of 5 Subteams

•January 2020

Founding of 10 Task Forces

Estimands in

January 2021

Recognized as EFSPI SIG

ASA

scientific

•June 2019

working

group

November 2018

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E9(R1) Finalization

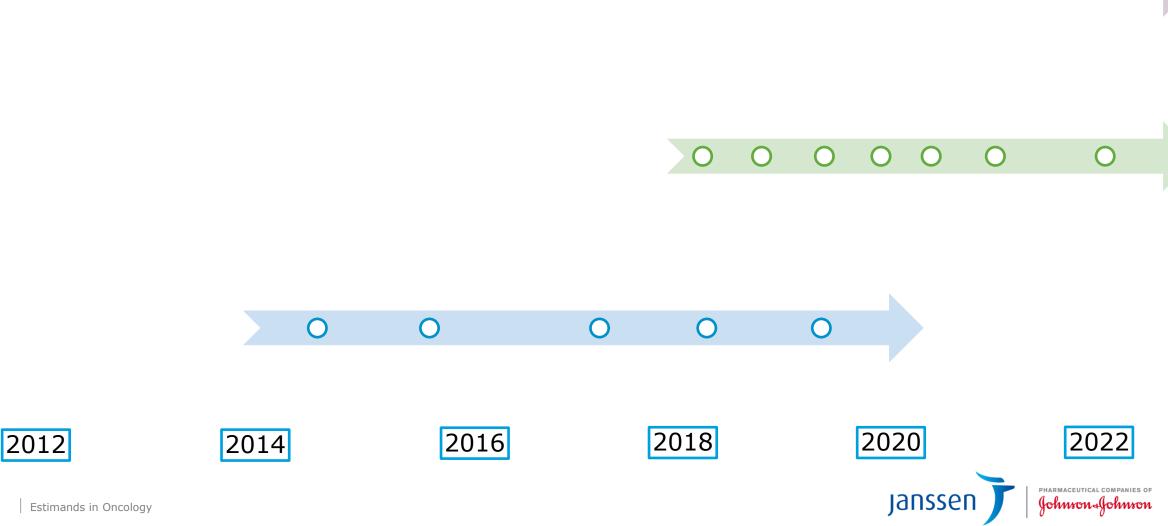
•November 2019

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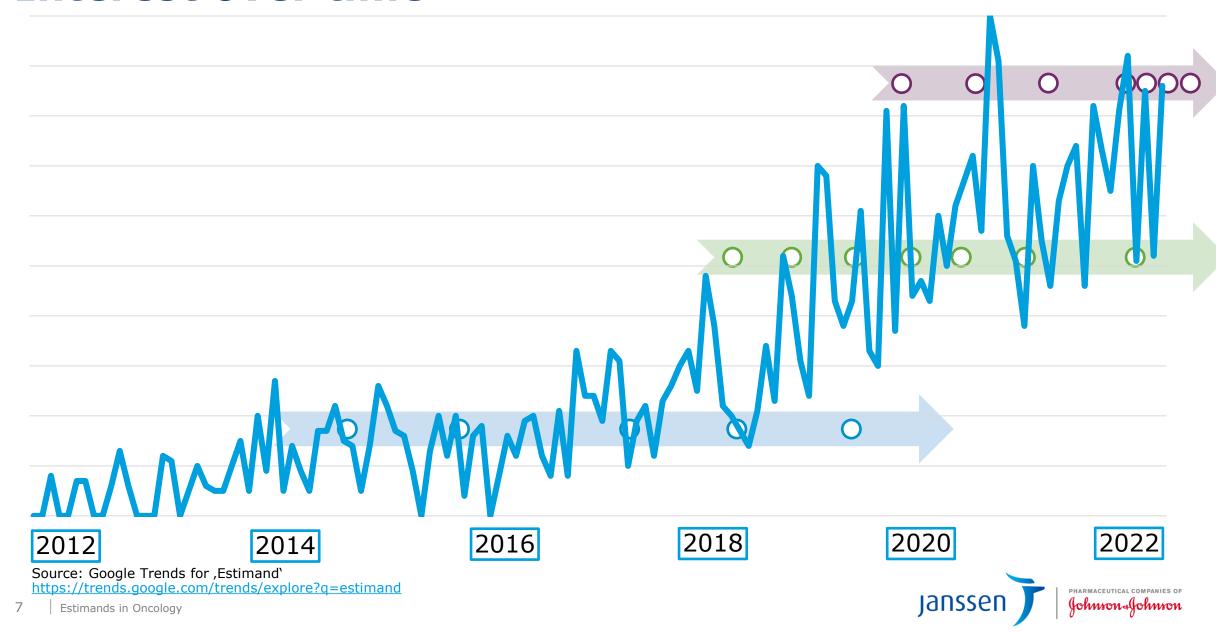
Assessing the Impact of COVID-19

• Jun 2020

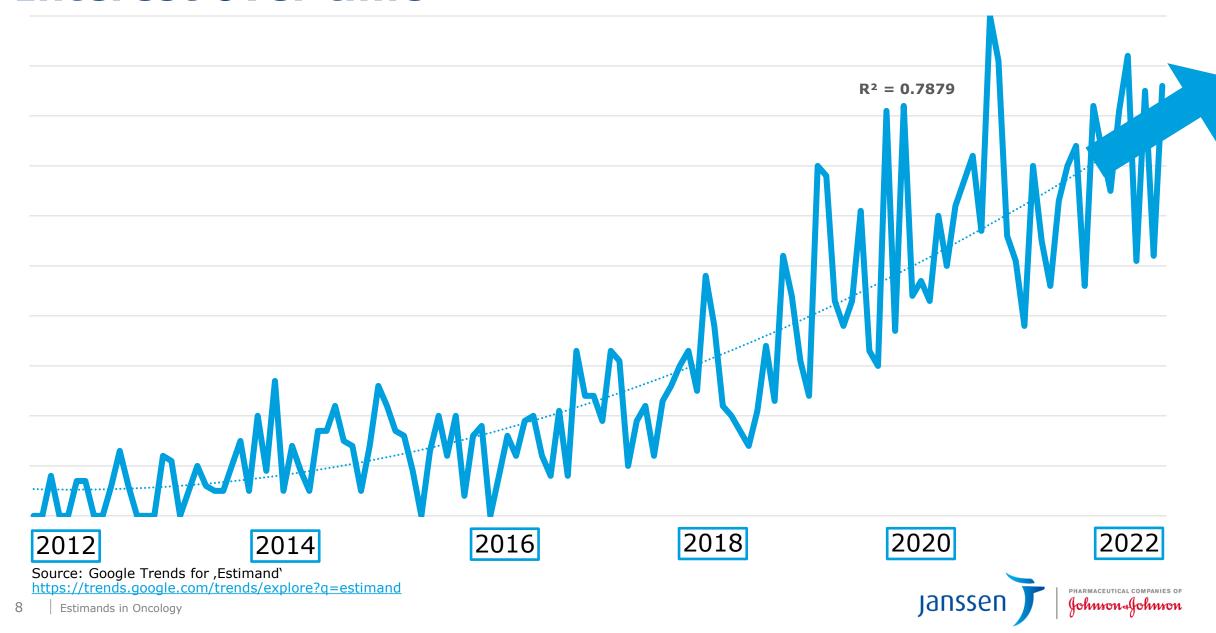
Timeline



Interest over time



Interest over time



Thank you

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Backup



Interest by region



TOP 5	Relative Score
United Kingdom	100
United States	81
Japan	45
Germany	45
Romania	34

MHLW/PMDA, Japan

JPMA

Founding Members of ICH

Source:

Google Trends for ,Estimand', past 12 months (https://trends.google.com/trends/explore?q=estimand) ICH Members (https://www.ich.org/page/members-observers)



FDA, United States

PhRMA

