



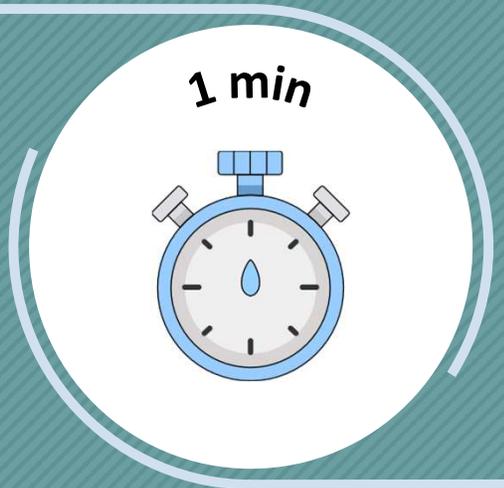
European Federation of Statisticians in the Pharmaceutical Industry
Promoting Professional Standards in Europe

Welcome to

12th EFSPI Statistical Leaders Meeting

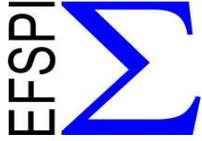
June 30 & July 1, 2021

Let's start with a warm welcome and reflect on why you are here today...



12th Statistical Leaders Meeting





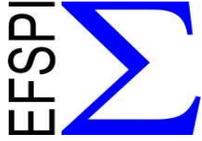
EFSPI



- EFSPI = European Federation of Statisticians in the Pharmaceutical Industry
- Founded in 1992
- EFSPI is an “umbrella”, non-profit making organisation
- A federation of 10 National European Groups
- No individual members
- Our national organisations collectively represent ~ 2200 members

EFSPI members



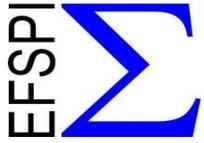


EFSPi Strategic Objectives



1. Represent the association members of EFSPi and provide a united and respected voice on key scientific, regulatory and statistical issues in drug development

- Develop program of scientific meetings and partner with association members to provide opportunities to discuss and align on key scientific, regulatory and statistical issues (responsible: Scientific Chair)
- Utilise EFSPi Statistics Leaders forum to discuss and align on emerging statistical areas and identify priorities and opportunities for EFSPi to lead/promote these areas in the health care environment (responsible: Statistics Leader Chair)



this is an EFSPI Meeting



- Please visit our website:

www.efspi.org

A screenshot of the EFSPI website homepage. The header features the EFSPI logo and the text 'EUROPEAN FEDERATION OF STATISTICIANS IN THE PHARMACEUTICAL INDUSTRY' and 'Representing Statistical Associations in Europe'. A navigation menu includes links for HOME, NEWS, ABOUT EFSPI, STATISTICS LEADERS MEETINGS, SIGS, PUBLICATIONS, EVENTS, ACTIVITIES, LINKS, ADVERTISEMENTS, CONTACT US, and MEMBERS. The main content area features a banner for an 'EFSPI / BBS WEBINAR: ESTIMANDS ADDENDUM IS FINAL! ANYTHING NEW FOR ONCOLOGY?' scheduled for Monday, 29th June 2020, 09:00-11:45. Below the banner are three columns of content: 'NEWS' with links to News Archive, Newsletters, and Blogs; 'INFO' with links to Who is EFSPI?, History, Member Groups, and Working Parties; and 'PUBLICATIONS' with links to Annual Reports, Strategy of EFSPI, Position Papers, and EFSPI Goals. On the right side, there is a search bar and sections for 'STATISTICS LEADERS FORUM' (with links to 10th Statistics Leaders Meeting and Previous Meetings) and 'WORKING GROUPS' (with links to Regulatory Affairs, Scientific Affairs, Communications, and Data Transparency). An 'OTHER LINKS' section is also present at the bottom right.

Organising committee

Justine Rochon
Vice President
Global Biostatistics and Data
Sciences
Boehringer Ingelheim



Chrissie Fletcher
Vice President
Development Biostatistics
GSK



Ingrid Sofie Harbo
Vice President
Biometrics
Lundbeck



Tina Christiansen
Corporate Vice President
Biostatistics
Novo Nordisk



Agenda Day 1

Time (CEST)	Subject	Presenter
13:00 – 13:15	Dial in & Welcome	Justine Rochon Stefan Driessen Tina Christiansen Ingrid Sofie Harbo
13:15 – 14:45 (90 min in total)	Career development and leadership skills for biostatisticians	
13:15 – 13:20 (5 min)	Introduction and recap of discussions at previous meetings and pre-meeting survey	Lars Endahl, Statistical VP, Novo Nordisk
13:20 - 13:35 (15 min)	Leadership skills development for biostatisticians	Anna Karina Trap Huusom, Senior Director, Biostatistics & Programming, Lundbeck
13:35 - 13:50 (15 min)	Career development for biostatisticians	Lars Endahl, Statistical VP, Novo Nordisk
13:50 - 14:05 (15 min)	Opponents view: are we making progress and if not, why?	Andy Grieve, Statistical Research Fellow, UCB
14:05 - 14:25 (20 min)	Discussions and sharing in break-out sessions	All
14:25 – 14:45 (20 min)	Panel discussion and sharing in plenum	Panel: Anna Karina Trap Huusom, Lars Endahl & Andy Grieve Moderator: Tina Christiansen

Time (CEST)	Subject	Presenter
14:45 – 15:00 (15 min)	Break	
15:00 – 16:00 (60 min in total)	Perspectives on use of clinical data in the regulatory review process and scientific advice by regulatory authorities	
15:00-15:45 (45 min)	Regulatory perspective	Jesper Kjær, Director of Division, Data Analytics Center (DAC) at DKMA & Frank Pétavy, Head of Methodology, EMA
15:45-16:00 (15 min)	Q&A	Moderator: Tina Christiansen
16:00 – 16:10 (10 min)	Break	
16:10 – 17:00 (50 min)	Social get-together online	All

Agenda Day 2

Time (CEST)	Subject	Presenter
13:00 – 13:10 (10 min)	Dial in & Welcome back	Ingrid Sofie Harbo Christine Fletcher
13:10 – 14:30 (80 min in total)	Data science versus Biostatistics in the pharmaceutical industry	
13:10 – 13:20 (10 min)	Introduction and recap of discussions at previous meetings	Ingrid Sofie Harbo
13:20 – 13:35 (15 min)	RSS Data Science Section: What has happened since the start in 2017	Jim Weatherall, VP Data Science and Artificial Intelligence R&D, Astra Zeneca
13:35 – 13:50 (15 min)	Visions for Data Science in the pharmaceutical industry	Thomas Senderovitz, SVP Data Science, Novo Nordisk
13:50 - 14:05 (15 min)	Special Interest Group in Data Science: Opportunities and challenges of Data Science in the pharmaceutical industry	Julia Chernova, Associate Director for Clinical Statistics, Bayer Pharmaceuticals
14:05 - 14:30 (25 min)	Q&A incl. panel	Panel: Julia Chernova & Justine Rochon Moderator: Ingrid Sofie Harbo

Time (CEST)	Subject	Presenter
14:30 – 14:45 (15 min)	Break	
14:45 – 15:45 (60 min in total)	Flexible workplace after Covid-19	
14:45 – 15:00 (15 min)	Introduction and present results from pre-meeting survey	Christine Fletcher
15:00 – 15:30 (30 min)	Discussions and sharing in break-out sessions	All
15:30 – 15:45 (15 min)	Sharing in plenum	Moderator: Christine Fletcher
15:45 – 16:00 (15 min)	Closing Remarks	Organizing committee



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Practicalities

House Rules for Teams Meeting



Be on time

Log / sign in in due time



Pay attention to your settings

Camera, headset, screen sharing, internet connection, and battery



Video must be ON

This is to promote focus



Mute your microphone

when you are not speaking



Respect the speaker

– stay present, and avoid multitasking



If you have **questions**, use the chat box or click the “raise hand” button

My Video – a small task for you

Mini-video clip gallery from EFSPI Statistics Leaders

What format?

A gallery of thoughts, statements, feedback about how YOU, as an EFSPI Stats Leader, benefited from the annual meeting and how you are committing to take action:

- Do it with your smartphone
- brief! (20 sec)
- your personal view
- inspirational and honest!

What content?

Feedback, e.g.

- What did you learn from the meeting?
- What did you like most?

Changes that YOU will implement, e.g.

- What is the first thing that I will start/stop doing/change in my team after the meeting?
- What am I excited about?

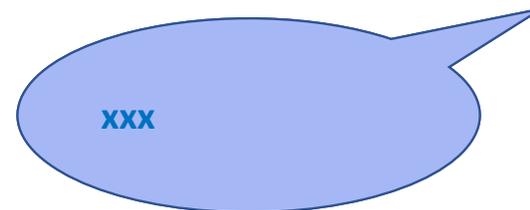
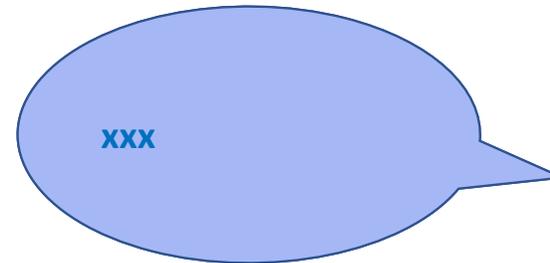
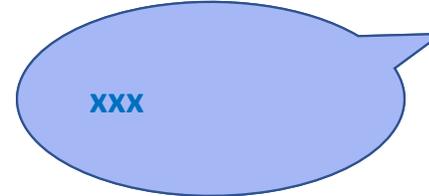
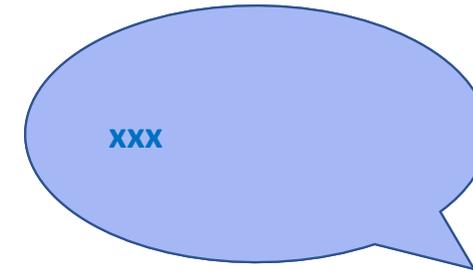
My Video – how & when

How?

- Videotape yourself **on your phone** for **20 seconds max**
- Please hold phone upright (portrait format)
- Send the clip to: EFSPI@mks.co.uk

By when?

- Right now! Spontaneously!
- Deadline is Monday, July 5th.





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Let's get started ...

Career development & leadership skills for biostatisticians

Lars Endahl
Statistical Vice President
Novo Nordisk



Topic:
Introduction and recap of discussions at previous meetings and pre-meeting survey

Career development for biostatisticians at Novo Nordisk

Anna Karina Trap Huusom
Senior Director Biostatistics & Programming
Lundbeck



Topic:
Leadership skills development for biostatisticians at Lundbeck

Andy Grieve
Statistical Research Fellow
UCB



Topic:
Opponents view: are we making progress and if not, why?

Discussions and sharing in break-out sessions



Timing: 20 min

Groups: You will be allocated directly in Teams to your break-out session so please, hang on

Material incl. template: Shared via mail this morning

Notetaker & presenter: Names available in the material (if somebody is missing quickly appoint someone else)

Survey results: Available in material

Plenum session will start again after 20 mins – be ready to share & ask question to the panel

You will be pulled back to the plenum session in Teams so please, hang on

Day 1 Break-out session

Group A	Group B	Group C	Group D	Group E
Frank Fleischer - notetaker	Chrissie Fletcher	Bruno Boulanger	Anna Karina Trap Huusom	Armin Schueler
Frank Langer	Daniele Compagnone - notetaker	David Wright - notetaker	Annamaria Muraro - notetaker	Giacomo Mordenti
Maria Dilleen - presenter	Emmanuel Zuber	Katrin Kupas	Christoph Gerlinger - presenter	Hans Ulrich Burger
Maylis Coste	Jens-Otto Andreas - presenter	Mette Milsgaard - presenter	CRAIG MCILLONEY	Michael O'Kelly
Rene Kubiak	Justine Rochon	Roland MARION-GALLOIS	Lars Endahl	Olavi Kilkku - notetaker
Stefan Driessen	Mark Whitlock	Tina Christiansen	Simon Cleall	Torsten Westermeier - presenter

BREAK

14:45 -15:00 (15 min)



Perspectives on use of clinical data in the regulatory review process and scientific advice by regulatory authorities

Jesper Kjær

Director of Data Analytics Centre
Danish Medicines Agency



Frank Pétavy

Head of Methodology, Data
Analytics and Methods Task Force
European Medicines Agency



After the presentations there will be time for questions

Please, use the 'raise your hand' function or write 'q' in the chat function



Remember to bring your favourite drink and a question, you always have wanted to ask your fellow statistical leaders

Break & Social get-together

Break: 16:00 - 16:10 (10 min)

Please, join Zoom 16:10 in order to be ready 16:15 for the first part of the social get-together:

***Online Magic and Mind Reading Show
With Duncan William***

Approx. **16:30 we will join Teams** again and there will be time for you to ask your question 😊



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Thank you for today
and see you tomorrow