

EFSPI 16th Statistics Leaders Meeting

12-13th May 2025, Ferring, Denmark

Agenda

Monday 12th May

Time (CEST)	Subject
1100 – 1130	Arrivals with coffee/tea
1130 – 1145	Welcome – Chrissie, Egbert, Kyle
1145 - 1200	Invited Guest: Jan Peutzfeldt, General Manager Ferring International PharmaScience Center
1200 – 1300	Icebreaker/Team activity Invited guests: Julie Funch Furberg, Farzaneh Safavimanesh, Signe Møgelmoose, Aksel Kaastrup Rasmussen, Christian Bjerregård Øland
1300 - 1345	Lunch
1345 - 1445	Keynote “The In-Silico Revolution in R&D: From Vision to Reality” Aaron Mitchell, Managing Principle, R&D Excellence, ZS
1445 - 1500	Networking break
SESSION 1: Academic Alliances: Universities and Pharma Nurturing NextGen Talent (Leads: Kyle, Anna, Mikala, Per, and Bjarke)	
1500 – 1505	Session introduction
1505 - 1535	Presentations from next gen statisticians (~30 minutes)
1535 - 1545	Small group discussions around tables (survey results provided as context for discussions) (~10 mins)
1545 - 1600	Guest Ingrid Sofie Harbo, VP Biometrics, Lundbeck: Fostering Synergy: Bridging Industry and Academia for Mutual Success Since 2007, Danish universities have been mandated to create Employer Panels (aftagerpanel in Danish) to cultivate a formalized dialogue between educational institutions and employers. The presentation is on how this collaboration can lead to a prosperous win-win scenario, benefiting both the academic world and the industry alike. (15min including questions)
1600 – 1635	Round Table discussions – breakout rooms
1635 – 1655	Networking break
1655 – 1725	Round Table debriefs and key actions for EFSPI Stat Leaders and EFSPi council
1715 - 1730	Close Day 1 and logistics for dinner – Emmanuel, Kyle
1730 – 1800	Hotel check-in
1800 – 1830	Transportation
1830 - 1930	Copenhagen walking tour
1930 - 2200	Dinner

Agenda

Tuesday 13th May

Time (CEST)	Subject
0800 - 0830	Arrival with coffee/tea
0830 – 0845	Welcome to Day 2, key reflections from Day 1 – Emmanuel
SESSION 2: Innovative clinical trial methodologies and their adoption - Priorities and Opportunities (Lead: Mouna, Kaspar)	
0845 – 0915	Session introduction
0915 – 1015	Round Table Discussions
1015 – 1035	Networking break with coffee/tea
1035 – 1115	Session 2 debriefs and key actions for EFSPI Stat Leaders and EFSPI council
1115 – 1215	Keynote “Accelerating patient focused drug development”, David Martin, VP Novartis, Global Head Patient Centered Outcomes CoE
1215 – 1300	Lunch
1300 – 1345	Site tour hosted by Elisabeth Hjertberg, Senior Research Technician, Early Sciences, Bioanalysis & Biomarkers. Pick up coffee/tea.
SESSION 3: Irrelevant and out of touch? (Leads: Frank, Simon)	
1345 – 1400	Session introduction
1400 - 1500	Round Table Discussions with coffee/tea
1500 – 1530	Session 3 debriefs and key reflections
1530 – 1545	Close Day 2: Summary and key highlights – Chrissie

European Federation of Statisticians in the Pharmaceutical Industry (EFSPI)

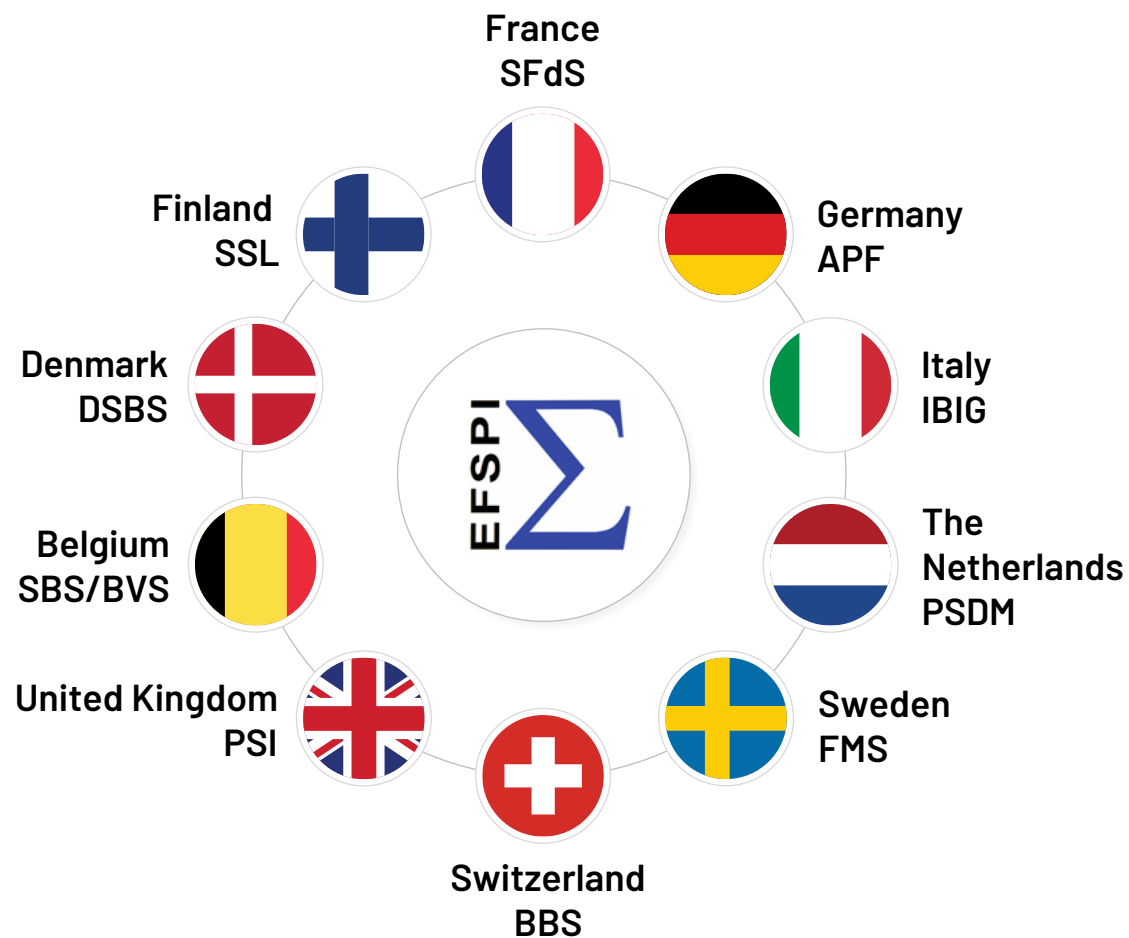
May 2025

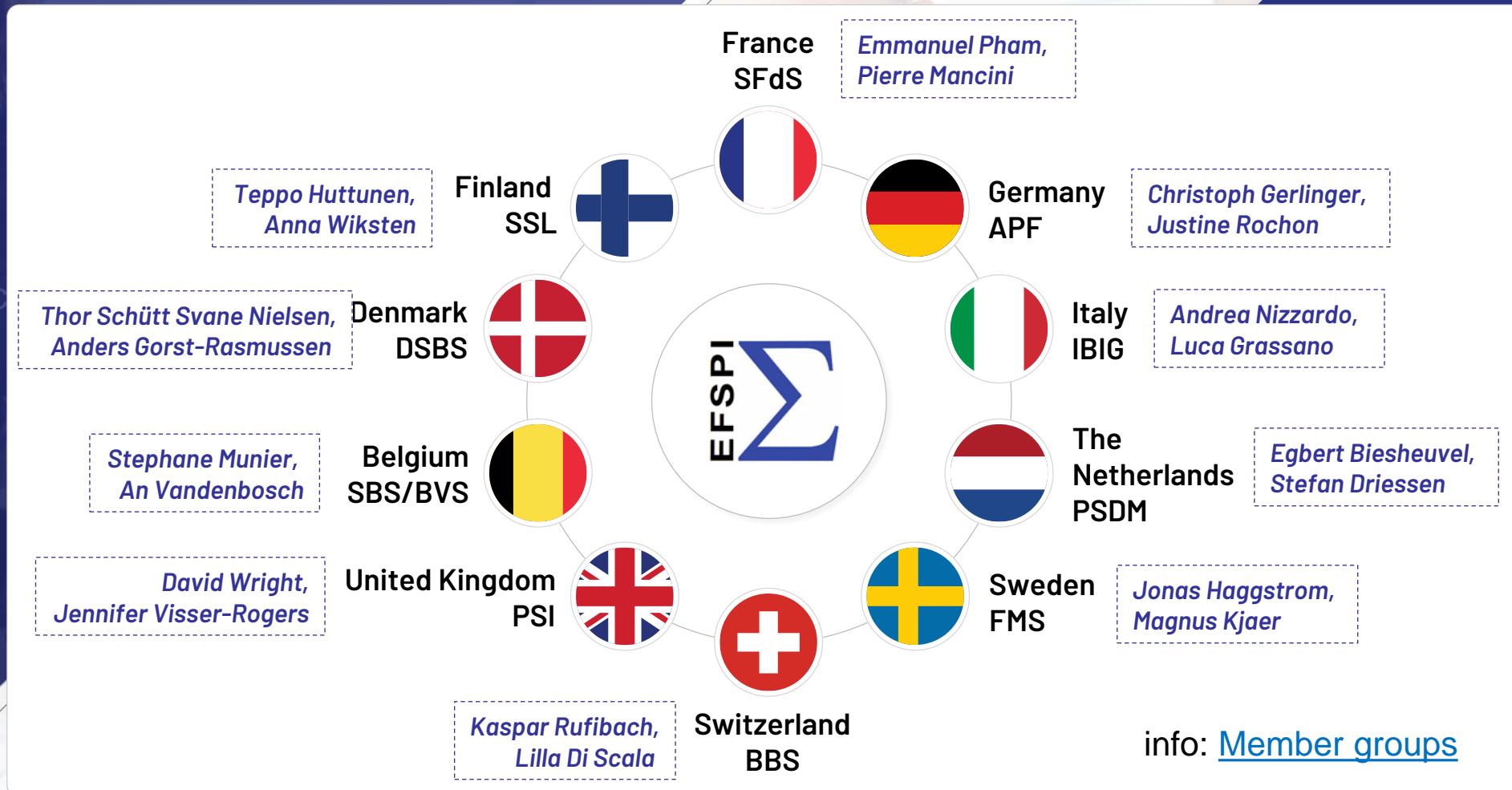
What is EFSPi?



- **EFSPi = European Federation of Statisticians in the Pharmaceutical Industry**
- Founded in 1992
- EFSPi is an “umbrella”, non-profit making organisation
- A federation of National European Groups
- Now have 10 national groups
- No individual members
- Our national organisations collectively represent 2200 members
- Each organisation has 2 members on the EFSPi Council
- Website: www.efspi.org

[Constitution](#)





EFSPI Objectives



→ To **promote professional standards of statistics** and the standing of the statistical profession in the pharmaceutical industry



→ To offer a **collective expert input on statistical matters** to national and international authorities and organisations



→ To **exchange information** on and **harmonise attitudes to the practise of statistics** in the European Pharma Industry and within member groups

EFSPI Officers and Key Roles

President –
Egbert Biesheuvel



Vice-President –
Justine Rochon



Treasurer –
*Teppo Huttunen**



Director (legal entity) –
Thor Schütt Svane Nielsen



** succeeded by Lilla di Scala in 2025*

Scientific Lead –
Jonas Haggstrom



Regulatory Lead –
Christoph Gerlinger



**Special Interest
Groups (SIGS) –**
Emmanuel Pham



**Statistical Methodology
Leaders –**
*Kaspar Rufibach, Mouna
Akacha, Cornelia Kunz*



Statistical Leaders Chair –
Christine Fletcher



Stats Regulatory Workshop
Vivian Lanius



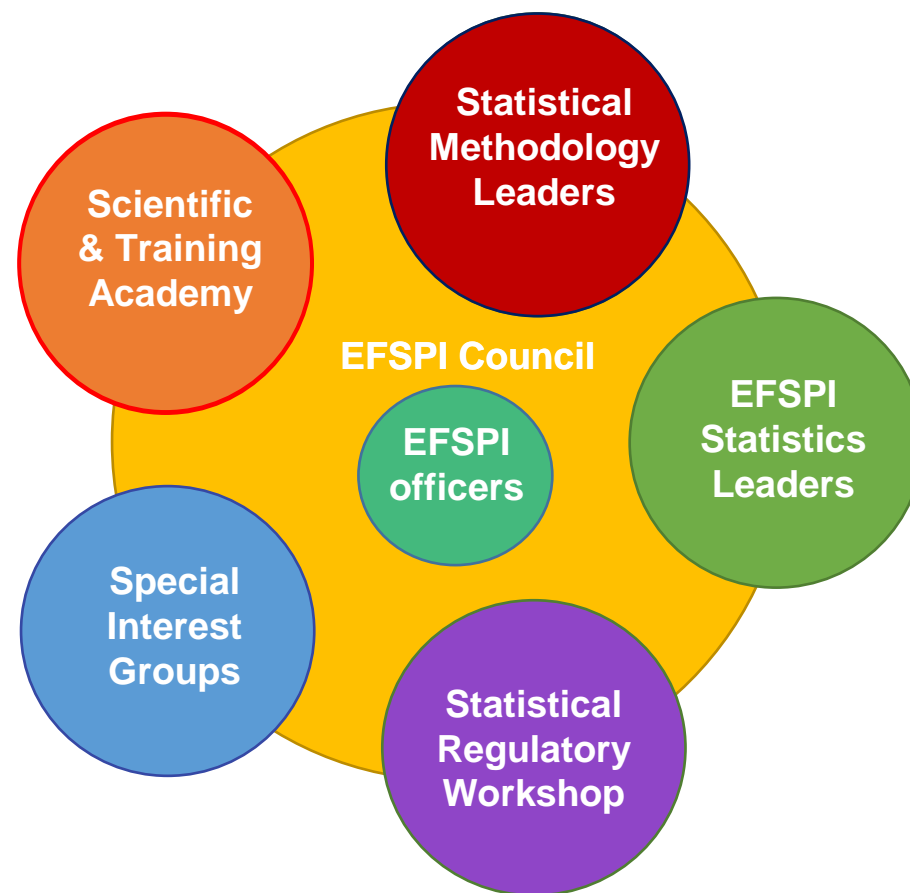
Communications Officer –
*Andrea Nizzardo,
Luca Grassano*



EFSPI Executive Office –
Hayley Wheatley, KSAM



Ecosystem



Software-Engineering
Patient-Focused-Drug-Development
Neuroscience-Estimands
Decision-Making
Data-Sharing AI&ML
Causal-Inference
RWD Biomarkers Pre-clinical
Launch&Lifecycle AIMS HTA Visualisation
Benefit-Risk Vaccines
Regulatory CSM/QLT Randomisation
Data-Science CMC
Historical-Data
Oncology-Estimands
Small-Populations
Subgroup-Analysis

10th EFSPI Regulatory Statistical Workshop

[Regulatory Workshop](#)

**10-12
September**



- Draft agenda available: regulatory priorities EU, ICH E20, Hierarchical Composite Endpoints, Target Trial Emulation, trial to Target population, ICH M15, Bayesian CT designs
- Possible to submit a short topic for discussion with a panel of regulators
- Registration fees at the same decent level (€280 / €70)
- Block booking for face-to-face attendance:
starting at 8400 Euro (up to 50 participants) – see website
- Block booking for unlimited virtual attendance:
2800 Euro (break-even with 40 colleagues)

<https://efspieurope.github.io/workshop/next.html>



EFSPI (European Federation of Statisticians in the Pharmaceutical Industry)

European Federation of Statisticians in the Pharmaceutical Industry
Pharmaceutical Manufacturing · St Albans, AL1 3TF · 3K followers · 0-1 employees

Stefan & 90 other connections follow this page

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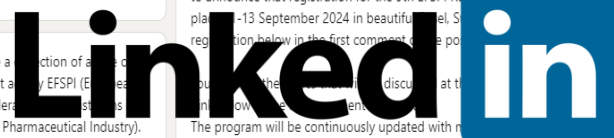
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EFSPI (European Federation of Statisticians in the Pharmaceutical Industry) 2,833 followers

9th EFPSI Regulatory Statistics Workshop – registration open

EFSPI (European Federation of Statisticians in the Pharmaceutical Industry) is happy to announce that registration for the 9th EFPSI Regulatory Statistics Workshop is now open. The workshop will take place on 12-13 September 2024 in beautiful Ferring, St Albans. Registration is free of charge. See a selection of slides from the past EFPSI Regulatory Statistics Workshop on the EFPSI website. The program will be continuously updated with more information. Check it out regularly.

[View ad library](#)



EFSPI EUROPEAN FEDERATION OF STATISTICIANS IN THE PHARMACEUTICAL INDUSTRY Representing Statistical Associations in Europe

16th Statistical Leaders Meeting
Monday 12th May – Tuesday 13th May 2025
Ferring, Amager Strandvej 405, DK-2770 Kastrup, Denmark

NEWS
Newsletters

INFO
Who is EFPSI?
History
Member Groups
Working Groups

PUBLICATIONS
Position Papers
Regulatory Comments

EVENTS
Upcoming Events
Events Calendar
Past Events

ACTIVITIES
National Member Groups
EMA Workshops

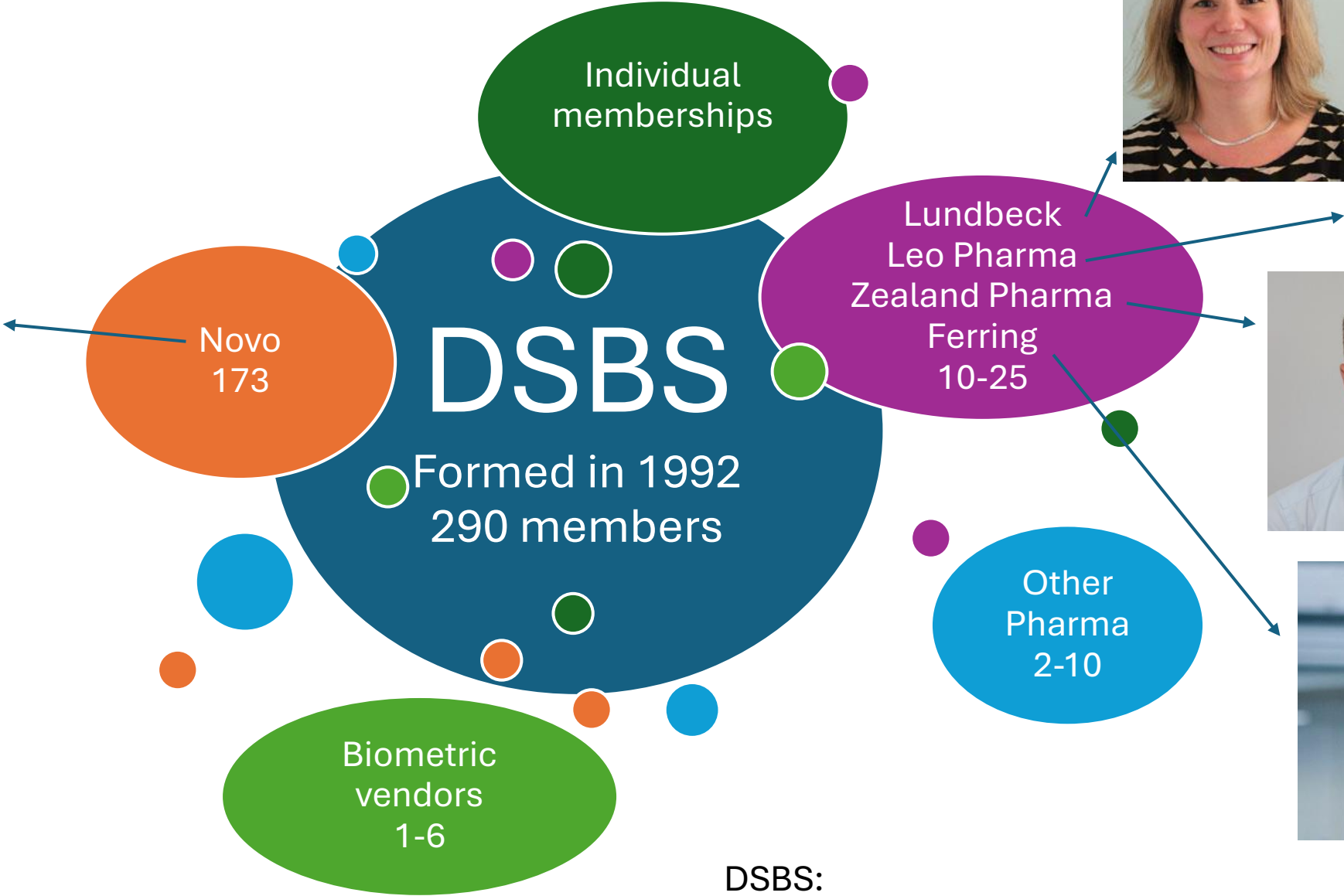
Statistics Leaders Forum
16th Meeting May 2025
Previous Meetings

Other Links
Regulatory Agencies
Regulatory Guidance
Statistical Organisations
Other Organisations
Statistical Journals


34+ Years Of Activity | 10 Countries | 2.800+ Statistician Members

Finally - New website!
- more control & Up-to-date

The DSBS members:



DSBS:
The Danish Society for Biopharmaceutical Statistics

A photograph of a family scene. In the foreground, an elderly man with white hair and a beard, wearing a blue denim shirt, is leaning forward and smiling at a baby. The baby, wearing a yellow dress, is reaching out with its hands towards the man. A woman wearing a wide-brimmed straw hat and a red top is holding the baby. In the background, a man with a beard and a patterned shirt is smiling. The scene is outdoors, possibly on a patio or balcony, with a blurred background.

Welcome to Ferring

Jan Peutzfeldt

Senior Vice President, Head of Region
Intercontinental and General Manager, Ferring
International PharmaScience Center

*Building families and
helping people live better lives*

Company overview



Privately owned, research-driven, specialty biopharmaceutical group committed to building families and helping people live better lives



Leader in reproductive medicine, and in specialty areas within gastroenterology and urology



At the forefront of innovation in uro-oncology intravesical gene therapy



Ferring has a full spectrum of products from conception to birth



Founded in Malmö, Sweden in 1950, headquartered in Switzerland



Global company with over 7,000 employees in more than 50 countries, and distribution in over 100 countries

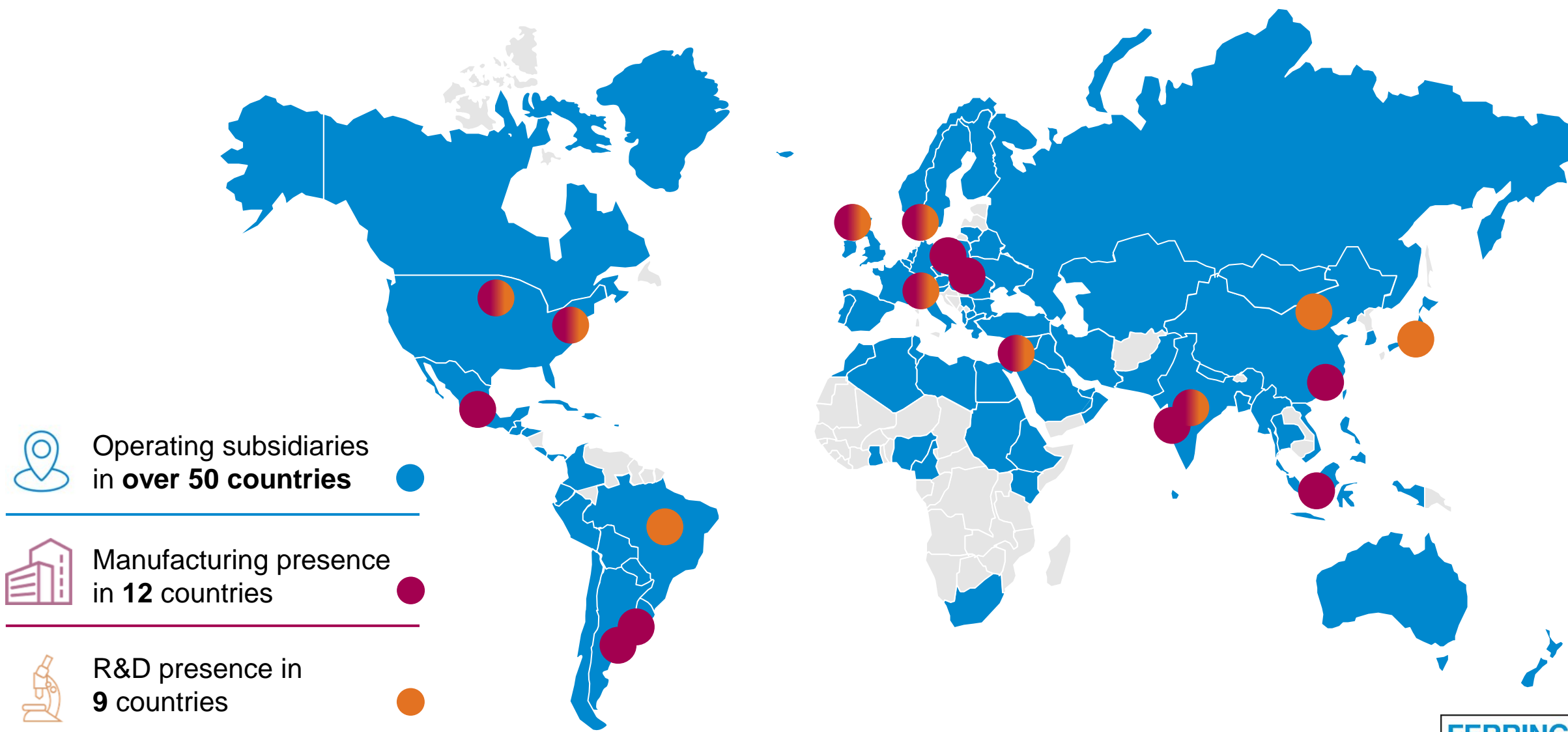


2024 revenue: EUR 2.3 billion*
2024 R&D investment: 16%

*USD 2.4 billion – CHF 2.2 billion



Global presence in over 100 countries



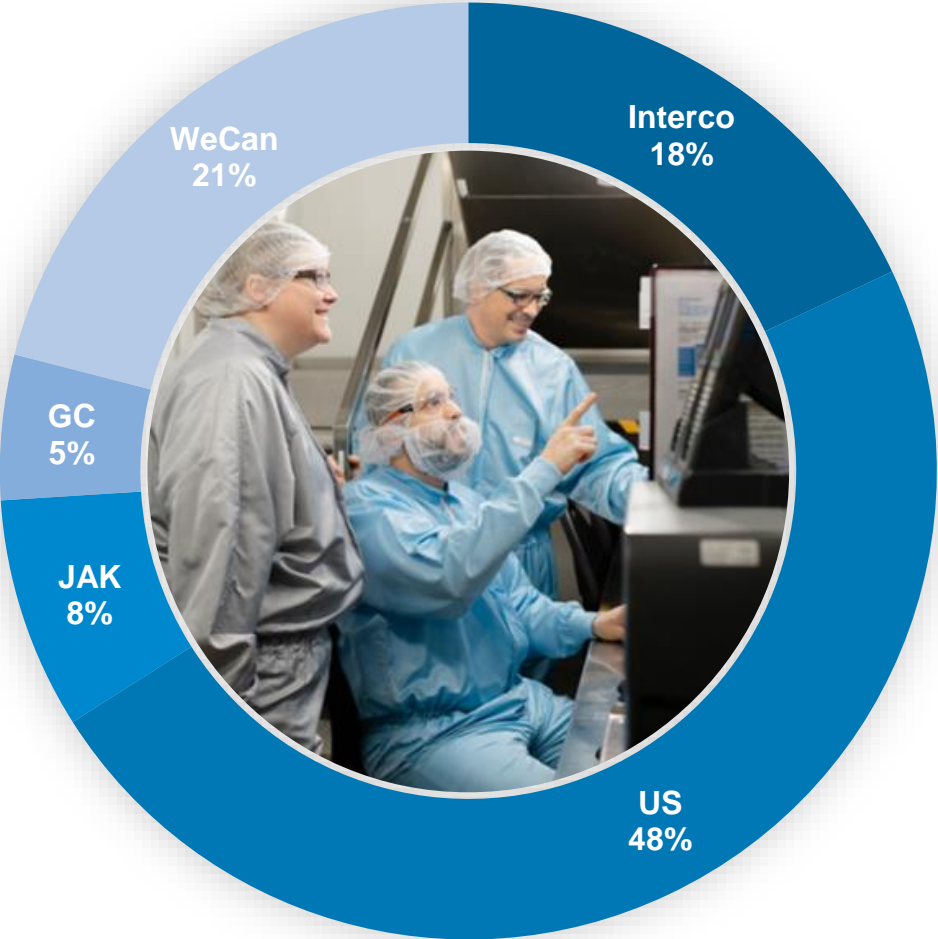
2024 revenue by region

Total revenue



2024 Revenues

EUR	2.3 billion
USD	2.4 billion
CHF	2.2 billion



US
United States

WECAN
Western Europe and Canada

Intercontinental
Rest of the World

JAK
Japan, Australia and Korea

Greater China
China, Hong Kong and Taiwan

2024 sales overview by therapeutic area



*Established Brands: These are considered to be brands with an established position in the market, which have a stable patient and customer base and are not promoted by our representatives.

Our R&D ambition



Reproductive Medicine

Advance our fertility leadership with the ambition to empower all aspiring parents to build families

Female and male infertility. Including related indications in maternal/women's health



Gastrointestinal conditions

Leveraging our breakthrough microbiota restoration therapy for *Clostridioides difficile* infection

Bring first-in-class biologic agents for the treatment of IBD and other gastrointestinal conditions



Uro-Oncology and Urology

Establish Adstiladrin® as the new standard of care and the backbone therapy in urothelial cancers

Build an innovative portfolio and pipeline in urological cancers

Project Family: Safe Birth



Nearly **90% of maternal deaths** from postpartum haemorrhage (PPH) occur in L&LMICs¹

- Project Family: Safe Birth aims to help protect the lives of 20 million women and their families by 2030 by reducing preventable maternal deaths from PPH.²
- Ferring works with partners, governments and stakeholders to make heat-stable Carbetocin Ferring available long term at a not-for-profit, affordable price to public and not-for-profit health facilities in low and lower-middle-income countries (L&LMICs).
- Carbetocin Ferring was our first product to receive WHO prequalification status.³ It is now registered in 25 countries, with further registrations in L&LMICs being prepared and planned.
- Since 2021, over 3 million doses of Carbetocin Ferring have been shipped for use in public and not-for-profit facilities in L&LMICs.
- A September 2023 *Fortune* article included Ferring in the 'Change the World' list of companies making a positive impact in addressing society's unmet needs, for our work in preventing PPH.⁴



©Joni Kabana, Kabana Photography/Paul Joseph Brown/Concept Foundation/Ferring Pharmaceuticals/MSD for Mothers

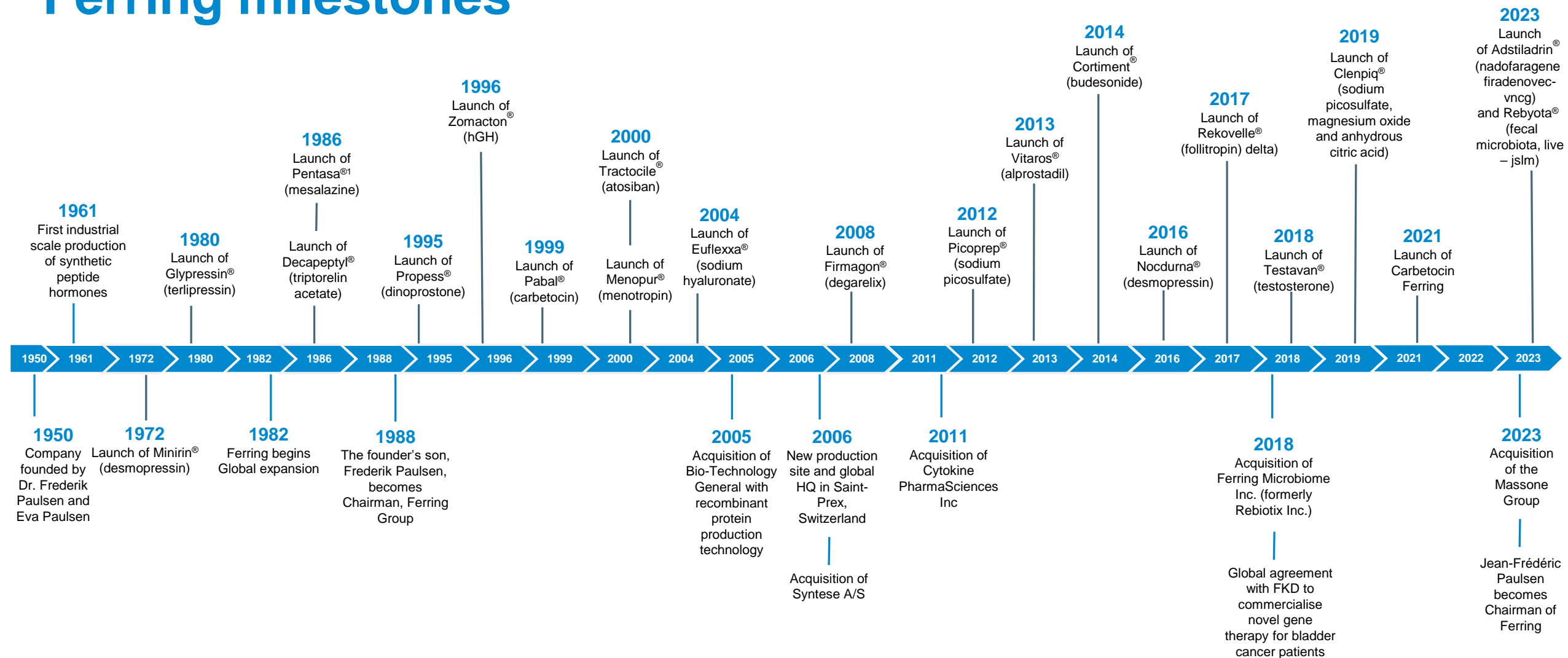
1. Weeks, A.D. (2024), Reducing maternal deaths from haemorrhage: Seeking the low-hanging fruit. BJOG, 131: 1025-1028. <https://doi.org/10.1111/1471-0528.17753>

2. World Health Organization. A Roadmap to Combat Postpartum Haemorrhage between 2023 and 2030. 2023. Available at https://cdn.who.int/media/docs/default-source/-health/maternal-health/pph-roadmap.pdf?sfvrsn=db36b511_3 Accessed April 2025.

3. WHO. First carbetocin prequalified <https://extranet.who.int/prequal/news/first-carbetocin-prequalified> Accessed April 2025.

4. Change the World List. Fortune. Available at: <https://fortune.com/ranking/change-the-world/2023/> Accessed April 2025

Ferring milestones



1. In the USA, Takeda markets Pentasa® under a trademark license from Ferring