

Harmonised approach to **E**arly **F**easibility **S**tudies for Medical Devices in the **E**uropean **U**nion (**HEU-EFS**)

M24 ANNUAL MEETING

15 – 16 September 2025,
Seminari Conciliar de Barcelona,
Spain

Venue: [Carrer de la Diputació, 231, L'Eixample, 08007 Barcelona, Spain](#)



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AGENDA

LINK TO JOIN VIRTUALLY

Monday, September 15th, 2025

11:30 – 12:30	Partner arrival, registration and light lunch
12:30 – 13:00	Welcome Rosanna Tarricone (UB, <i>virtual</i>), Andrea Rappagliosi (Edwards Lifesciences, <i>virtual</i>), Laura Sampietro-Colom and Xavier Luria (Clinic Barcelona); Geraldine Joanny (IHI, <i>virtual</i>).
13:00 – 13:40	Overview of the HEU-EFS project <ul style="list-style-type: none"> • <i>Where we are today - Giuditta Callea (UB) (20 min)</i> • <i>Summary of recommendations from WP1&2 - Marta Kerstan (J&J, <i>virtual</i>), Tom Melvin (University of Galway) (20 min)</i>
13:40 – 14:25	WP3 Methodology development: rationale, processes, and procedure <ul style="list-style-type: none"> • <i>Overview of key regulatory pathways in the EU – Alexandra Herborg Cornelius Poulsson (NIPH) (15 min)</i> • <i>Results of interviews with NCAs, with a focus on best practices implemented across the EU – Federico Facciolo (UB) (15 min)</i> • <i>Proposed process for EFS in the EU – Kevin Drisko (Edwards Lifesciences) (15 min)</i>
14:25 – 14:40	<i>Coffee break</i>
14:40 – 15:10	WP3 Methodology development: rationale, processes, and procedure <ul style="list-style-type: none"> • <i>Q&A and discussion with NCAs (30 min) moderated by Alexandra Herborg Cornelius Poulsson (NIPH)</i>
15:10 – 15:40	WP3 Methodology development: rationale, processes, and procedure <ul style="list-style-type: none"> • <i>Q&A and discussion with AB, PAG, and consortium (30 min) moderated by Karin Fricke (Edwards Lifesciences)</i>

15:40 – 16:15	WP4 Methodology development: evidence requirements, data, and statistical tools <ul style="list-style-type: none"> <i>Presentation of Clinical Investigation Plan and checklist</i> - Monica Tocchi (Meditrial, <i>virtual</i>), Donatella Mariani (Meditrial), Alessandra Denaro (Abbott) (15 min) <i>Q&A and discussion with AB, PAG, and consortium</i> (20 min)
16:15 – 16:30	<i>Short break</i>
16:30 - 17:15	WP8 Web portal, dissemination, exploitation, and communication <ul style="list-style-type: none"> <i>Overview of results and plans</i> - Fanny van der Loo (Edwards Lifesciences) (15 min) <i>Guidelines for scientific publications</i> - Giuditta Callea (UB) (15 min) <i>Q&A and discussion with AB, PAG and consortium</i> (15 min)
17:15-17:55	Guest speech by Flora Giorgio (European Commission – DG SANTE) <ul style="list-style-type: none"> <i>Presentation</i> (20 min) <i>Discussion</i> (20 min)
17:55 – 18:00	Closing and information regarding social dinner Laura Sampietro-Colom (Clinic Barcelona)
18:00 – 18:45	<i>Video shooting</i>
19:30 – 21.30	Social dinner at Hotel Zenit Borrell (address: Comte Borrell, 208 - 08029 Barcelona)

Tuesday, September 16th, 2025

08.25 – 08.30	Opening 2nd day Giuditta Callea (UB), Fanny van der Loo (Edwards Lifesciences)
08:30 – 08:40	Patient Engagement Plans implementation Yasemin Zeisl (EPF) and Marta Bragagnolo (GHH)
08:40 - 09:35	WP6: Ethical and Legal aspects <ul style="list-style-type: none"> • <i>Presentation of templates and checklists for Informed Consent Form and Master Clinical Trial Agreement, and guidelines for Insurance Agreement</i> Diana Panzica and Francesco Malandrini (UB), Irene Gonzales (Edwards Lifesciences, virtual) (15 min) • <i>Q&A and discussion with PAG and patients' organisations</i> (20 min) • <i>Q&A and discussion with AB and consortium</i> (20 min)
09:35 - 10:10	WP5 Program Monitoring System <ul style="list-style-type: none"> • <i>Presentation of proposed key performance metrics and dashboard –</i> Federico Facciolo and Francesco Malandrini (UB), Alessandra Lo Scalzo (AGENAS) (15 min) • <i>Q&A and discussion with AB, PAG and consortium</i> (20 min)
10:10 – 10.45	WP7 Testing the methodology and piloting <ul style="list-style-type: none"> • <i>Presentation of criteria guiding pilot EFS</i> Fanny van der Loo (Edwards Lifesciences) and Manon Gielkens (Medtronic) (15 min) • <i>Q&A and discussion with AB, PAG and consortium</i> (20 min)
10:45 – 11:05	Coffee Break
11:05 – 11:35	General discussion with AB, PAG, and consortium
11:35 – 12:10	WP9 Project management and scientific supervision (PARTICIPATION LIMITED TO CONSORTIUM MEMBERS) Francesca Pissarello (UB) <ul style="list-style-type: none"> • <i>Presentation: upcoming deliverables, 2nd year technical report, continuous reporting, amendment, next steps</i> (15 min) • <i>Q&A and discussion with consortium</i> (20 min)
12:05-12:30	Recap, next steps and closing Giuditta Callea (Bocconi University) and Fanny van der Loo (Edwards Lifesciences)
12:30-13:30	<i>Standing lunch and video shootings</i>



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