Status: March 02, 2026 – initial draft version

11th EFSPI Regulatory Statistics Workshop

19 – 20 August 2026

Basel Switzerland

Preliminary topics:

- Regulatory updates / strategic priorities in pharmaceutical development
- EMA draft guideline on non-inferiority and equivalence comparisons in clinical trials
  Clarification of intent of the guideline.
  Comments/pain points from the industry perspective.
  Highlights and updates since public consultation.
- What can we learn from the first JCA procedures?
  Learn from the how the methodological guidance has been implemented in early JCAs and what this means for future assessments
- Proper Planning and Interpreting Treatment Effect Heterogeneity
- Baseline Covariate Adjustment for Treatment Effect Estimation
- Clinical endpoints – surrogate/early/intermediate endpoints
- Synthetic data
- Short topic session – popular short topic session with a panel of regulators, possibly combined with a reversed short topic session where regulators pose questions to industry

Day 0: 18th August 2026, 19:00-22:00

19:00 – 22:00	**Pre-Conference Regulatory Dinner** *All regulators and HTA assessors* are cordially invited to this (self-paid) event, organized by <NN> and <NN>. For more information and registration please visit **link**.

Day 1: 19th August 2026, 08:30-17:30 (+1:30h get-together)

Time	Presentation
08:30 – 08:45 (15 min)	**Opening Remarks** Anna Wiksten (EFSPI President, BMS, CH)
08:45 – 10:00 (75 min)	**SESSION TITLE <SESSION 1>** <*brief* description, purpose of the session> *Chairs: NN (affiliation, country code), NN (affiliation, country code)* Talk 1: NN (affiliation, country code): Titel of the presentation Talk 2: NN (affiliation, country code): Titel of the presentation Q&A with the audience, the speakers and regulatory agency representatives: NN (affiliation, country code), NN (affiliation, country code)
10:00 – 10:30 (30 min)	Coffee break

Day 1: 19th August 2026, 08:30-17:30 (+1:30h get-together) *<continued>*

Time	Presentation
10:30 – 12:30 (120 min)	**Short Topics**: **Present a problem on 2-3 slides and receive input from a panel** (≤ 20 minutes per topic) *Chairs: NN (affiliation, country code), NN (affiliation, country code)* Panelists: (*MWP member, #[alternate] SAWP member) NN (affiliation, country code), NN (affiliation, country code), NN (affiliation, country code), NN (affiliation, country code), NN (affiliation, country code), … Topic 1: NN (affiliation, country code): Title Topic 2: NN (affiliation, country code): Title Topic 3: NN (affiliation, country code): Title Topic 4: NN (affiliation, country code): Title Topic 5: NN (affiliation, country code): Title Topic 6: NN (affiliation, country code): Title
12:30 – 14:00 (90 min)	Lunch break and poster session: ESIGs and EFSPI Working Groups
14:00 – 15:30 (90 min)	**SESSION TITLE <SESSION 2>** <*brief* description, purpose of the session> *Chairs: NN (affiliation, country code), NN (affiliation, country code)* Talk 1: NN (affiliation, country code): Titel of the presentation Talk 2: NN (affiliation, country code): Titel of the presentation Talk 3: NN (affiliation, country code): Titel of the presentation Q&A and moderated discussion with the audience, the speakers and the panelist: NN (affiliation, country code)
15:30 – 16:00 (30 min)	Coffee break
16:00 – 17:30 (90 min)	**SESSION TITLE <SESSION 3>** <*brief* description, purpose of the session> *Chairs: NN (affiliation, country code), NN (affiliation, country code)* Talk 1: NN (affiliation, country code): Titel of the presentation Talk 2: NN (affiliation, country code): Titel of the presentation

	Talk 3:	NN (affiliation, country code): Titel of the presentation
	Q&A	and moderated discussion with the audience, the speakers and the panelist: NN (affiliation, country code)
17:30 – 19:00	**Get-together** including … organised by NN (affiliation, country code) and NN (affiliation, country code)	

Day 2: 20th August 2026, 09:00-17:30

Time	Presentation	
09:00 – 10:30 (90 min)	**SESSION TITLE <SESSION 4>** <*brief* description, purpose of the session>	
	Chairs:	*NN (affiliation, country code), NN (affiliation, country code)*
	Talk 1:	NN (affiliation, country code): Titel of the presentation
	Talk 2:	NN (affiliation, country code): Titel of the presentation
	Talk 3:	NN (affiliation, country code): Titel of the presentation
	Q&A	and moderated discussion with the audience, the speakers and the panelist: NN (affiliation, country code)
10:30 – 11:00 (30 min)	Coffee break	
11:00 – 12:30 (90 min)	**SESSION TITLE <SESSION 5>** <*brief* description, purpose of the session>	
	Chairs:	*NN (affiliation, country code), NN (affiliation, country code)*
	Talk 1:	NN (affiliation, country code): Titel of the presentation
	Talk 2:	NN (affiliation, country code): Titel of the presentation
	Talk 3:	NN (affiliation, country code): Titel of the presentation
	Q&A	and moderated discussion with the audience, the speakers and the panelist: NN (affiliation, country code)
12:30 – 14:00 (90 min)	Lunch break	

Day 2: 20th August 2026, 09:00-17:30 *<continued>*

Time	Presentation
14:00 – 15:30 (90 min)	**SESSION TITLE <SESSION 6>** <*brief* description, purpose of the session> *Chairs: NN (affiliation, country code), NN (affiliation, country code)* Talk 1: NN (affiliation, country code): Titel of the presentation Talk 2: NN (affiliation, country code): Titel of the presentation Talk 3: NN (affiliation, country code): Titel of the presentation Q&A and moderated discussion with the audience, the speakers and the panelist: NN (affiliation, country code)
15:30 – 16:00 (30 min)	Coffee break
16:00 – 17:30 (90 min)	**SESSION TITLE <SESSION 7>** <*brief* description, purpose of the session> *Chairs: NN (affiliation, country code), NN (affiliation, country code)* Talk 1: NN (affiliation, country code): Titel of the presentation Talk 2: NN (affiliation, country code): Titel of the presentation Talk 3: NN (affiliation, country code): Titel of the presentation Q&A and moderated discussion with the audience, the speakers and the panelist: NN (affiliation, country code)
17:30 – 17:40	**Closure** Vivian Lanius (UCB BioSciences GmbH, Local Organizing and Scientific Committee, DE)

Poster session of ESIGs and EFSPI Working Groups on Day 1 (19th August 2026, 12:30 – 14:00)

ESIG/EFSPI Working Group	**Title**	**Author(s)/*Presenter*(*s*)** *on behalf of the SIG / group
SIG …	xxx	NN, …