

# APF Workshop 27-November-2026

## Use Cases for AI in Statistics & Baseline Covariate Adjustment

### hosted by Elderbrook Solutions GmbH:

Maritim Hotel am Schlossgarten Fulda  
Pauluspromenade 2  
36037 Fulda

### Pre-event Dinner:

26th November: IDEAL Fulda - Café · Restaurant · Bar  
Rabanusstraße 12  
36037 Fulda

Registration for the workshop and pre-event get-together is required

Link for registration will follow soon

### Agenda

| Time                                                           | Topic                                                                                              | Presenter                                                                    |
|----------------------------------------------------------------|----------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|
| 08:00 – 08:45                                                  | Coffee Break & Welcome                                                                             | -                                                                            |
| 08:45 – 09:00                                                  | Opening Remarks                                                                                    | Michaela Kohring<br>(Elderbrook Solutions GmbH),<br>Frank Langer (Eli Lilly) |
| <b>Block A: Use Cases for AI in Statistics (09:00 – 13:30)</b> |                                                                                                    |                                                                              |
| 09:00 – 09:10                                                  | Welcome & AI Introduction                                                                          | Hannes Buchner<br>(Staburo GmbH)                                             |
| 09:10 – 09:40                                                  | From Biomarkers to Better Trials:<br>Increasing Clinical Success Rates with an AI-Powered Platform | René Kubiak<br>(Sanofi)                                                      |
| 09:40 – 10:10                                                  | Automatisation of TLFs: an AI assisted workflow                                                    | Fabian Hellbach,<br>Daniel Schreyer<br>(Staburo GmbH)                        |

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|-------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------|
| <b>10:10 – 10:40</b>                                                    | Coffee Break                                                                                                                                                              | -                                                                                                                                      |
| <b>Time</b>                                                             | <b>Topic</b>                                                                                                                                                              | <b>Presenter</b>                                                                                                                       |
| <b>10:40 – 11:10</b>                                                    | AI Use Cases in Biostatistics: SAS Code Generation, SAP Automation, and HTA Dossier Analysis!                                                                             | Detlef Nehrdich<br>(DN Beratung)<br>Franziska Eidloth<br>(DATAN Analytics)<br>Benedikt Langenberg<br>(BL Analytics)                    |
| <b>11:10 – 11:40</b>                                                    | An LLM-Assisted Approach to Standardisation and Validation for Multi-Market Submissions                                                                                   | Marvin Fischer<br>(Eli Lilly)                                                                                                          |
| <b>11:40 – 12:00</b>                                                    | Discussant / Panel Discussion / Q&A                                                                                                                                       | Armin Schöler (BfArM)                                                                                                                  |
| <b>12:00 – 13:00</b>                                                    | Lunch Break                                                                                                                                                               | -                                                                                                                                      |
| <b>13:00 – 13:30</b>                                                    | APF-Status updates                                                                                                                                                        | Frank Langer, Thomas Bregenzer, Frank Fleischer, Cornelia Kunz, Jens-Otto Andreas, Susanne Schäfer, René Kubiak                        |
|                                                                         | Mentoring-/Mentee-Initiative                                                                                                                                              | Prof. Dr. Meinhard Kieser<br>(IMBI Heidelberg)                                                                                         |
|                                                                         | Academia Meets Industry                                                                                                                                                   | Cornelia Kunz<br>(Boehringer Ingelheim Pharma GmbH & Co. KG)                                                                           |
|                                                                         | EFSPI-Update                                                                                                                                                              | Vivian Lanius<br>(Boehringer Ingelheim Pharma GmbH & Co. KG)<br>Stefan Englert<br>(Johnson & Johnson)                                  |
| <b>Block B: Baseline Covariate Adjustment / PROCOVA (13:30 – 16:30)</b> |                                                                                                                                                                           |                                                                                                                                        |
| <b>13:30 – 14:05</b>                                                    | Some Intricacies of Covariate Adjustment for Binary Endpoints                                                                                                             | Martin Schnürch,<br>Jannik Hammerschmied,<br>Christian Stock<br>(Boehringer Ingelheim Pharma GmbH & Co. KG)                            |
| <b>14:05 – 14:40</b>                                                    | Combining AI/ML-Based Prognostic Scores Across Missing-by-Design Historical Data: A Simulation Study on Super-Covariate Adjustment in Alzheimer's Disease Clinical Trials | Jan Wiemer<br>(Sanofi)                                                                                                                 |
| <b>14:40 – 15:10</b>                                                    | Coffee Break                                                                                                                                                              | -                                                                                                                                      |
| <b>15:10 – 15:45</b>                                                    | Is it worth investing into borrowing external control data when complimentary covariates already provide precision gains for randomized trials?                           | Heiko Götte<br>(Merck KGaA)                                                                                                            |
| <b>15:45 – 16:30</b>                                                    | Panel Discussion + Q&A                                                                                                                                                    | Presenters and additional panellists:<br>Cornelia Kunz (Boehringer Ingelheim Pharma GmbH & Co. KG), Stefan Englert (Johnson & Johnson) |

**16:30 End of the meeting**