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

Decentralised trials

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Acknowledging input from Chrissie Fletcher (GSK) and other industry colleagues

Statistical considerations with DCTs

- **Remote versus clinic assessments:**
  - **What level of evidence is required to justify that remote assessments can be considered to be as reliable as clinic assessments?**
  - **What additional information is needed to address sources of variability?**
  - **What level of exploration/analysis is needed to assess potential bias?**

- **Decentralised recruitment:** Has the potential to enable a more representative patient population to be enrolled in clinical trials than has historically achieved.
  - **What expectations do regulators put on Sponsors if they choose to recruit patients in a decentralized fashion?**

- **Missing data:** Some data are missing in virtually all clinical trials.
  - **Do regulators have any specific additional concerns about missing data in a decentralised trial?**

Statistical considerations with DCTs

- **Hybrid vs full decentralised clinical trials:** A hybrid approach rather than a fully decentralised trial is more likely to be proposed.
  - **Do regulators have any specific considerations when a clinical trial is completely virtual compared with a mix of on site and virtual? For example, how much freedom can be given to participants to choose whether and when they come to a site for assessment or are assessed virtually?**
- **Link with digital endpoints:** Some decentralised elements require alternative methods of data collection (for example using an app to collect symptom scores remotely). Digital endpoints and apps used to collect outcome data evolve (are updated) over time.
  - **What level of evidence is required to demonstrate that the updates have not affected the reliability of the data collected?**
- **Link with digital endpoints:** Many of these endpoints provide a much richer data source per patient than was possible with once a visit data collected on site. But with the richer information source comes statistical questions such as which summary measure to use.
  - **Do regulators have any advice on the level of investigation needed to develop and justify the chosen summary measure?**
- **Conclusion: All of these questions point to the need for advice on how to systematically evaluate the impact the DCT elements have on data quality and integrity.**