Round Table Discussion

Involvements of statisticians in drug discovery and early stages of clinical development

EFSPI 10th Statistical Leaders Meeting

July 4, 2019

TR**V**E or F**X**LSE?

- Statistics & data science is the key discipline to make use of the enormous amount of data from different sources and to evaluate drug candidates with a holistic approach.

- However, we are used to looking at data piece by piece and to hand over results and decisions step by step along the value chain from research to clinical development to commercialization.

- In order to accelerate regulatory approvals and patient access, we need to transform our core business which currently is clinical development and go beyond it, especially get Statistics in earlier (i.e. research/preclinical development).

- Some companies have established groups of statisticians and data scientists in drug discovery and early stages of clinical development.

40 mins. Discussion

➢ Is this an important topic for yourself and why?

➢ Is this a new area for statisticians?

➢ Do we already have the skills/competencies to be successful in this area?

➢ How much is your department engaged in this topic?

➢ Which obstacles do you expect?

➢ How can they be mitigated?

➢ What do we need to do to implement this idea?

Summary for 5–7 mins. plenary feedback

➢ Is this an important topic for yourself and why?

-
-
-

➢ What do we need to do to solve/implement it?

-
-
-