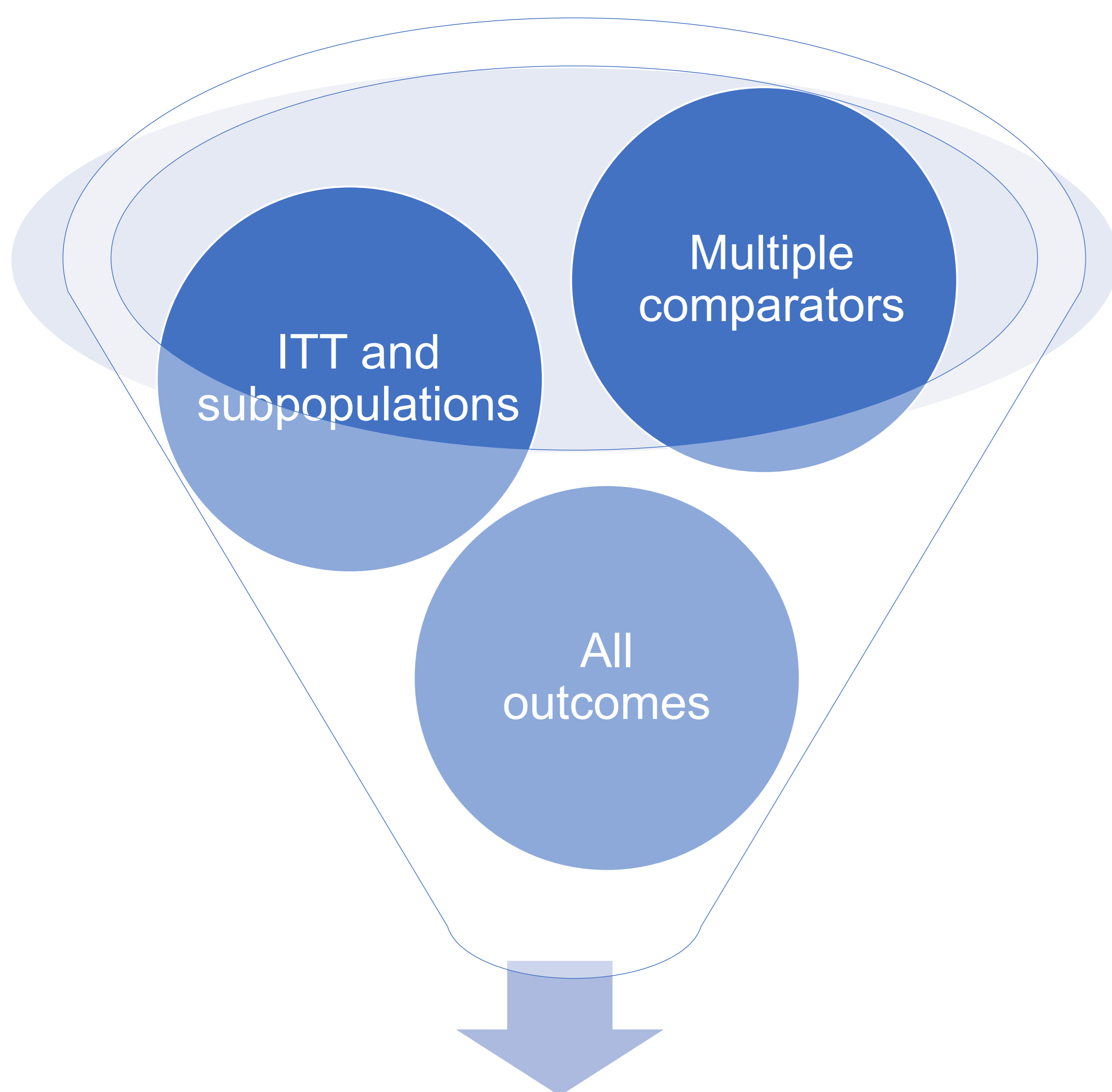


# EU HTA – How can statisticians help navigate the problem of multiplicity?

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## *Multiple stakeholders, multiple perspectives, multiple comparisons – but **one** Joint Clinical Assessment*



**Final scope for JCA dossier**

### What to expect?

- Comparative analyses for *all* outcomes, including safety
- PICOs that include multiple subpopulations and subgroups

### Setting

- Endpoint hierarchy cannot be predefined due to different member state needs
- Indirect treatment comparisons (ITC) for most of the PICOs
- HTA goal is quantification of treatment benefit, not hypothesis testing
- Formal multiplicity adjustment, therefore rarely desirable or feasible

### What can we as statisticians do?

- Educate stakeholders to possibly reduce scope of statistical analyses
- Preplan, where possible, to avoid data-driven decision-making
- Continuous development of ITC methodology to reduce bias
- Help stakeholders not overstate the strength of evidence, by providing statistical and scientific interpretation of analyses of subpopulations/subgroups and granular endpoints (eg, AE preferred terms)

## Conclusions

Statisticians will play a crucial role to help navigate the pitfalls around the multiplicity in the JCA. They should be prepared to engage early and participate proactively in the planning and interpretation of the analyses with multiple stakeholders!