1) Session Title: **QSP Modelers – Take Your Data Seriously, Not Literally!**

2) Proposed Session Format:
- Individual Talk – 20 minutes

3) Chairperson(s)'s name, title, affiliation, contact information, and ISoP membership status

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4) Description of the session, including background and scientific importance

QSP models use a variety of data, from in vitro to clinical, to inform model development and calibration. But what does it mean for the QSP model to "match the data"? The ways in which data are best utilized are not always straightforward and may not lend themselves well to parameter-by-parameter reference attributions. Data are often scarce, leaving knowledge gaps that require scientific judgment. It can be difficult to extrapolate from in vitro to in vivo, or from the pre-clinical to clinical setting. Finally, significant differences in study results can arise due to disparate methodologies, as well as inherent patient variability. Such challenges require scientific sensitivity to the context, type, and appropriateness of available data. This session will introduce several common scenarios wherein taking data too literally could result in inappropriate representations or misleading results. We recommend alternative data use approaches that are appropriate to the given data landscape when deriving and inferring parameter values or constraints on QSP model behavior.

5) Learning objectives

The audience will learn to take a broader view of data used for QSP modeling and learn approaches to use data appropriately.