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Early findings of the working group on nonadherence in clinical trials

- The main focus of the workgroup is on study-related nonadherence.
- The impact, of nonadherent subjects on clinical trial success will be elucidated.
- Professional and duplicate subjects, subject registries, compliance markers, PK sampling and compliance technologies will be described
- We will look at where and how to act to account for or reduce nonadherence, at each stage of a clinical trial: Prescreen, screening, post-randomization, post-hoc analysis, see Fig 1.
- Regulatory and statistical aspects of defining the ITT and eliminating non-compliant subjects from the data set will be discussed. Are randomized subjects proven to have never taken IP part of the ITT?
- The goal of the working group is to produce a white paper, and perhaps an ISCTM session, on nonadherence in 2016.

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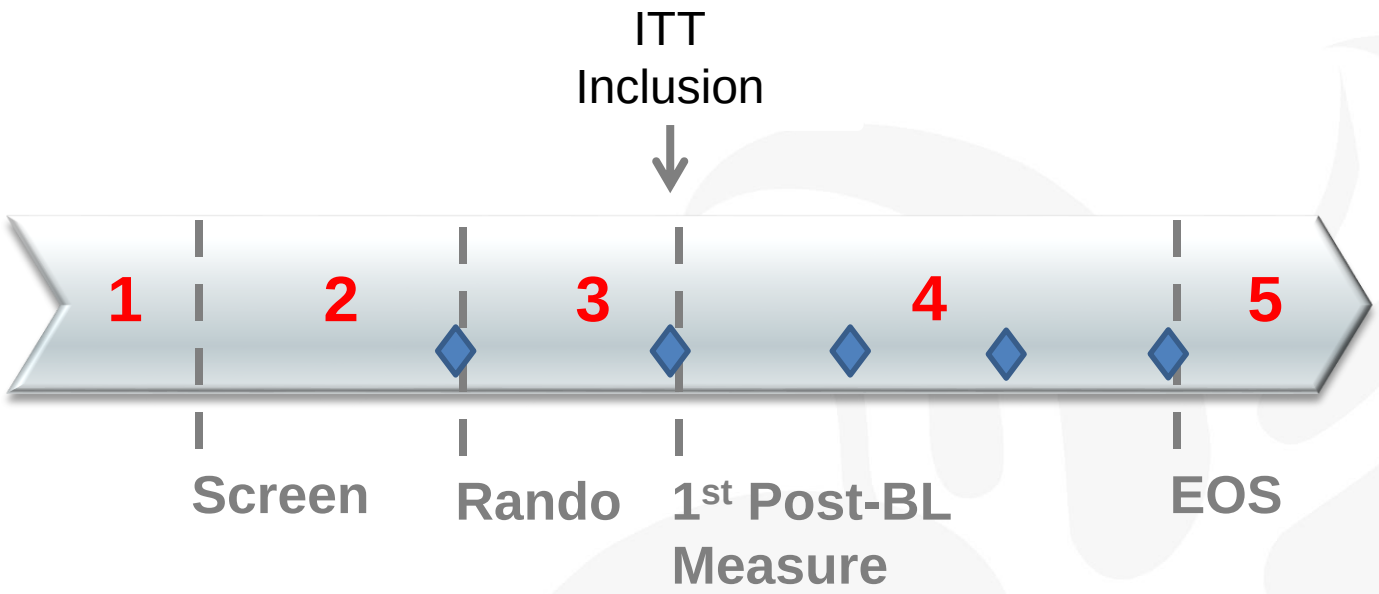
Fig. 1 Where to act to reduce/ account for nonadherence?



1 – Pre-Screening
2 – Screening
3 – Before 1st Post-Baseline Scale
4 – After 1st Post-Baseline Scale
5 – End of Study/Post Hoc Analysis