

## The 12 Phases of the Biostatistics Collaboration Process:

### *Initial Collaboration Phases*

- 1** The investigator ensures that the question has scientific relevance, poses it to the biostatistician, and provides clinical background information.
- 2** The biostatistician brainstorms with the study team about the question being posed, the primary outcomes, possible data available, and discusses feasibility.
- 3** The investigator sends background materials (e.g. study objective, preliminary hypotheses; relevant publications; list of relevant variables) so the statistician can become familiar with the scientific background and literature.
- 4** As the collaboration progresses (via meetings/correspondence with the biostatistician), the nature of the project, study design, objectives, and hypotheses are clarified. Expectations of the collaborative roles and authorship are discussed.

### *Statistical Analysis and Dissemination Phases*

- 5** Expertise and advice on randomization, data collection, database design, and data provenance are provided.
- 6** A statistical analysis plan (SAP) is created, discussed, and agreed upon, derived variables are defined, and data consistency checks are specified.
- 7** The statistician and investigator meet/correspond regularly to ensure that the project is progressing and to keep the team updated.
- 8** Data collection is finalized, an analysis dataset with derived variables is created, and final data consistency checks are implemented.
- 9** Analyses per SAP are conducted, properly documented, and a statistical report is provided which includes interpretations of all results.
- 10** Results are discussed with the investigator. Additional data requests may be addressed – but the main hypotheses are expected to remain unchanged.
- 11** When a project results in a publication, the statistician writes the statistical methods section, and critically reviews the entire manuscript to ensure correct reporting and interpretation of results. For typical projects, biostatisticians will be included as co-authors.
- 12** Throughout the entire collaboration, the Biostatistician maintains documentation of all analyses to allow for full reproducibility of their work and extend the original knowledge base. At study conclusion, documentation is organized for potential dissemination.