

## Appendix 1: Technical Approaches to Support the Correct Attribution of Data Collected Using Digital Health Technologies in the Field

This appendix lists technical approaches that are being successfully implemented at the time of publication, as revealed by our evidence gathering activities. It is beyond the scope of this work to suggest which approaches may be appropriate for a particular study, but per the [recommendations](#), 1) technical approaches to mitigating data attribution concerns should be secondary to efforts that promote correct data attribution through study design and digital technology selection, and 2) sponsors should engage participants in decisions regarding the inclusion of technical approaches to ensuring data attribution. Finally, it is important to note that the practices listed here are likely to evolve rapidly with both experience and technological advances.

### Authentication at the Point of Digital Technology Use

The following authentication processes may be used prior to digital technology use and data capture:

- ▶ Password protection
- ▶ Biometric authentication
  - Fingerprint
  - Retina (eye) scan
- ▶ Multi-factor authentication
  - Requires the user to have two of the following: 1) something they know (a password/PIN, a security question, etc), 2) something they are (for example, something biometric like a finger print), and 3) something they have (a card, token or code sent via SMS etc.)

### Monitoring, Programming and Statistical Approaches

The following processes may be used to detect potentially mis-attributed data after it has been collected:

- ▶ Software programs that monitor data with the purpose of detecting randomness
- ▶ Trend analysis
  - Example: A digital technology is measuring heart rate, and during the first few weeks of the study a participant's average HR over 24 hours was 82bpm, varying between 60bpm and 90bpm during a typical day. If, during week 4, this same participant's digital technology is capturing an average HR of 70, varying between 65bpm and 72bpm, trend analysis should indicate that this data may not be originating with the study participant to whom the technology was assigned.
- ▶ Clustering techniques
  - Clustering is a process of partitioning a set of data into meaningful sub-classes, called clusters. Clustering techniques support the understanding of the natural grouping or structure in a data set, including providing insight into clusters of data that may be mis-attributed.