d) Sensors and Wearables

The growing availability of affordable and reliable mobile Health (mHealth) technologies including wearables and sensors is driving the interest of many pharmaceutical companies. The need and the appetite to collect data directly from patients is rising. The recent evolutions include the desire to:

1. Support the implementation of remote trials,
2. Ensure ongoing safety oversight,
3. Collect different objective endpoints, and
4. Reduce patient burden by leveraging available data and technologies (e.g. applying BYOD beyond mobile phone to include smart watches and home intelligent devices).

Some CDM organizations may see the collection of continuous and large volumes of data as a costly and unsurmountable challenge. Other organizations see it as a robust way to collect real-time, untampered and high-quality data eliminating issues from error prone manual processes. Regardless, CDM should establish a clear and proactive strategy. Below are some considerations:

- Sensors and Wearables data are eSource by nature since they are collected directly from the patient and stored electronically first. As stated in the SCDM eSource white paper, one of the seven principles of eSource is "Control for Quality". While "in the world of electronic records, it is possible to control the integrity of data seen or modified by many parties over the life time of the records" it "requires a very thoughtful implementation of systems of controls working together"[13]. CDM must establish "the data chain of custody (e.g., understanding how the data are generated), how the data are connected to other devices or networks, and who has access to the data after it is generated and stored on a device or server before it reaches the data management team" [14].

  It is also worth acknowledging that not all eSource are equal. As an example, sensors and wearables are very different from eSource collected from eCOA. Like EDC, eDiaries and eCOA offer online edit checks upon entry. Some companies are using web-based forms as eDiary and eCOA back-ups in case the device is malfunctioning. None of that is applicable for sensors and wearables. There is no way to go back in time to collect lost data. In cases where sensors and wearables are critical to the study, it may be advisable to ensure that patients have rapid access to back-up device(s).

- Sensors and wearables generate high volume of data (millions to trillions of times more than EDC) at high velocity (i.e. generated continuously multiple times per second). In this context, traditional CDM processes would not be viable. No organization would agree to provide thousands of times more resources and budget to manage cleaner data collected directly from the patients. However, it is expected that CDM monitors the data flow efficiently to rapidly identify safety and data signals.

  An implausibly low pulse of 12 recorded on the eCRF would be handled by edit checks. Needless to say, CDM must implement more sophisticated data monitoring tools to identify sudden changes in data patterns from wearables. One missing wearable value out of hundreds of thousand on a given day is likely insignificant. A sudden rise in a resting pulse up-to 120 beats per minute that was previously recorded as 85 may be a safety risk or may be explained by the fact that the patient ran across the parking lot prior to arriving for the visit. It is therefore important to define up-front escalation paths and alert levels when managing fast paced and high data volume.

While those are a few considerations, it highlights the need for different approaches and technologies.