U.S. Food and Drug Administration (FDA)
Center for Devices and Radiological Health (CDRH)
Patient Engagement Advisory Committee (PEAC) Meeting
Hilton Washington DC North/Gaithersburg

FDA Discussion Questions

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With the evolution of the internet, patients and consumers are developing and participating in many independently created and populated data sources, including social media platforms, patient-driven registries, and using digital health technologies such as activity trackers and other sensors. This information presents many potential opportunities for utilization in the regulatory arena but it should be fit-for-purpose.[1] Some challenges with the use of patient-generated health data include the statutory requirement that information used in regulatory decision-making be valid scientific evidence.[2] To address some concerns about whether this information could be used as valid scientific evidence, FDA is requesting your recommendations about whether patient-generated health data could be fit-for-purpose in a regulatory context.

Questions:

1. The FDA's postmarket regulatory activities include advising manufacturers on the development of postmarket studies (including defining the study design, patient population, and outcomes of interest), performing surveillance for adverse events, issuing recalls, and communicating signals to the public. How do you think patient-generated health data should be used, if at all, to inform these postmarket processes for medical devices (that is, fit-for-purpose) listed below. Please specify the opportunities and challenges of its use for each:
    a. inclusion of these data in formal postmarket studies;

[1] "Fit-for-purpose" means that the information is of sufficient quality to provide confidence in the analyses necessary to inform or support regulatory decision-making..

[2] According to 21CFR860.7(b)(4), valid scientific evidence is evidence from well-controlled investigations, partially controlled studies, studies and objective trials without matched controls, well-documented case histories conducted by qualified experts, and reports of significant human experience with a marketed device, from which it can fairly and responsibly be concluded by qualified experts that there is reasonable assurance of the safety and effectiveness of a device under its conditions of use. The evidence required may vary according to the characteristics of the device, its conditions of use, the existence and adequacy of warnings and other restrictions, and the extent of experience with its use. Isolated case reports, random experience, reports lacking sufficient details to permit scientific evaluation, and unsubstantiated opinions are not regarded as valid scientific evidence to show safety or effectiveness. Such information may be considered, however, in identifying a device the safety and effectiveness of which is questionable.

b. surveillance for adverse outcomes; and
c. issuing recalls and signal management.

2. Potential challenges that exist for using patient-generated health data to inform regulatory activities include the following:
    - Results that do not reflect the true outcomes, stemming from problems selecting the study population, designing the study, or analyzing the data;
    - Data quality and integrity (for example missing data, duplicated patients, fake patients, manipulation of data); and
    - Applicability of the information to all patients living with the condition

    a. Are there other considerations unique to patient-generated health data that were not mentioned?
    b. Please provide your thoughts about approaches to mitigate these challenges for each type of patient-generated health data:
        i. Social media,
        ii. Sensor-related data, and
        iii. Patient-driven registries data.

3. Internet-connected digital health technology and social media could be used to identify people living with certain medical conditions and under-represented populations for inclusion in clinical trials for medical devices. Please provide your thoughts on the following topics:
    a. Researchers using this approach to identify and recruit patients for clinical studies;
    b. Privacy issues with this approach to clinical trial recruitment;
    c. Tools where users give active permission (e.g., blogs, social media communities) versus tools where users passively give permission (e.g., search tool analytics);
    d. Data collected from digital health technology (including sensors and activity trackers) for one purpose and used for medical research.

4. What practices would you want to be put in place to protect patients' privacy? Should websites include language to inform patients about all possible uses of their data including medical research?

5. FDA communicates to the public using our FDA website, Facebook posts, YouTube, email blasts to subscribers, blogs, and Twitter. What other mechanisms or approaches would you like the FDA to use to communicate information about medical devices?

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