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Request for Information on the National Digital Twins R&D Strategic Plan

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Domain of These Comments

These comments are written from the perspective of **medical digital twins (MDT)**. They may apply in other domains, but they were not written to apply to all domains where Digital Twins might be applied.

Definition of "Digital Twin" and need for data collection

The definition of a "Digital Twin" (DT) in the Request for Information omits a key part of all digital twins*: a central data repository that shares data*. In other domains, an individual DT always constantly draws data from a central repository aggregating current data from all active DTs. At the same time, all individual DTs supplies data back to the central repository so that the aggregate of DTs can be kept up to date with the most recent data describing both the individual and the population. *If this is not done, then the system is not a DT.* Data sharing and aggregation present significant challenges in data security and patient privacy, but an effort must be made to overcome these challenges if the promise of DTs is to be fully realized. Note that data sharing is the ONLY method of validating that the DTs work in the real world. It is the ONLY way to correct and refine deployed DTs.

During the Covid pandemic, aggregated medical data from smart watches showed promise in being able to detect pre-symptomatic Covid in individuals, and predict rising infection rates in populations[1]. Data collected was limited by the technology of the smart watches and included only heart rate, sleep patterns and walking patterns. But even that sparse data showed promise. Note that a rising *local* infection rate is the type of data that should be fed back to the individual's DT to help provide the best interpretation of the individual's own data and their best course of action. This is an example where the DT must send data back to the central repository, and that data must be made available for other instances of the DT.

[1] Mishra, T. *et al.* Pre-symptomatic detection of COVID-19 from smartwatch data. *Nat Biomed Eng* **4**, 1208–1220 (2020). https://doi.org/10.1038/s41551-020-00640-6

Ownership of digital twins

One issue I have not seen discussed in the domain of medical digital twins (MDTs) is the issue of ownership. **Who owns an MDT?** Who owns the data collection device(s)? Who owns the MDT host computer system? Who owns the data? Who owns the predictions?

HIPPA would suggest that the patient owns their own data, but HIPPA does not address ownership of devices or computer resources. Ownership is of critical importance to medical care providers (physicians, hospitals), medical device manufacturers (suppliers), insurers (payers), and to patients (customers and end users). Clearly, there will be different scenarios with each perhaps having different ownership patterns.

One case might be a digital twin deployed in a critical care unit for a sepsis patient. In this case the sensors, data collection pipeline, data repository, digital twin code, computing system, user (physician) interface, etc. are likely owned by the hospital. The payer for the system, in the USA, is likely an insurer. The patient's data is of course owned solely by the patient. But the rest of the MDT environment is owned by someone else.

Contrast that with an individual wearing a MDT equipped smart watch or carrying a smart phone. In this case, the sensors, data collection stream, MDT software and user interface all belong to the patient. (The system might be paid for by an insurer, but the purchased system would still belong to the patient.) What if (or "can") the MDT provider lock down access to the system? This is often seen in complex deployed software systems such as self-driving cars where the "owner" has no access or control over the software. In this case does the patient "own" their own MDT system? Clearly then, "ownership" of a smart device MDT is significantly different than "ownership" in a clinical setting.

Regulatory issues for personally owned Digital Twins

Medical devices, defined here as any device that **claims to have medical utility**, are strictly regulated. Therefore, devices in a clinical setting are regulated. A personal MDT deployed on a smart device and owned wholly by an individual, may or may not have medical claims. Existing digital personal monitors that claim medical utility (e.g., clinically relevant EKG recordings, or the "artificial pancreas") are regulated as medical devices. On the other extreme, the maker's claims may be sufficiently vague and include a footnote disclaimer ("These claims have not been verified by …") as is often seen in unregulated claims on the health benefits of dietary supplements. Does a smart watch that monitors the wearer's motion and detects they have been sedentary for too long, and suggests the wearer get up and move, a regulatable device? At what point do these personal device hosted MDTs become regulated devices?

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