

PDUFA VII Goals For Digital Health Technologies – A Technical Perspective

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Learning Objectives

- Identify key actions CDER is taking to support the use of DHT-generated data for drug development
- Recognize the types of DHT data relevant to application submissions
- Understand the value and challenges of DHT High Frequency (HF) data

PDUFA VII Performance Goals



IT related goals for Digital Health Technologies

- a. By end of Q2 FY 2023, FDA will **enhance its internal systems** to support review of DHT-related submissions including capturing key information about clinical trials utilizing DHTs to support tracking the number and rate of change of DHT-related submissions.
- b. In FY 2023, FDA will establish a secure cloud technology to enhance its infrastructure and analytics environment that will enable FDA to effectively **receive, aggregate, store, and process** large volumes of data from trials conducted using DHTs.
- c. After establishing the cloud environment, FDA will **pilot a secure cloud-based** mechanism to support submission and review of DHT-generated data sets.
- d. FDA will work to enhance, recommend and implement **standards** that reduce the handling necessary to make data analyzable.

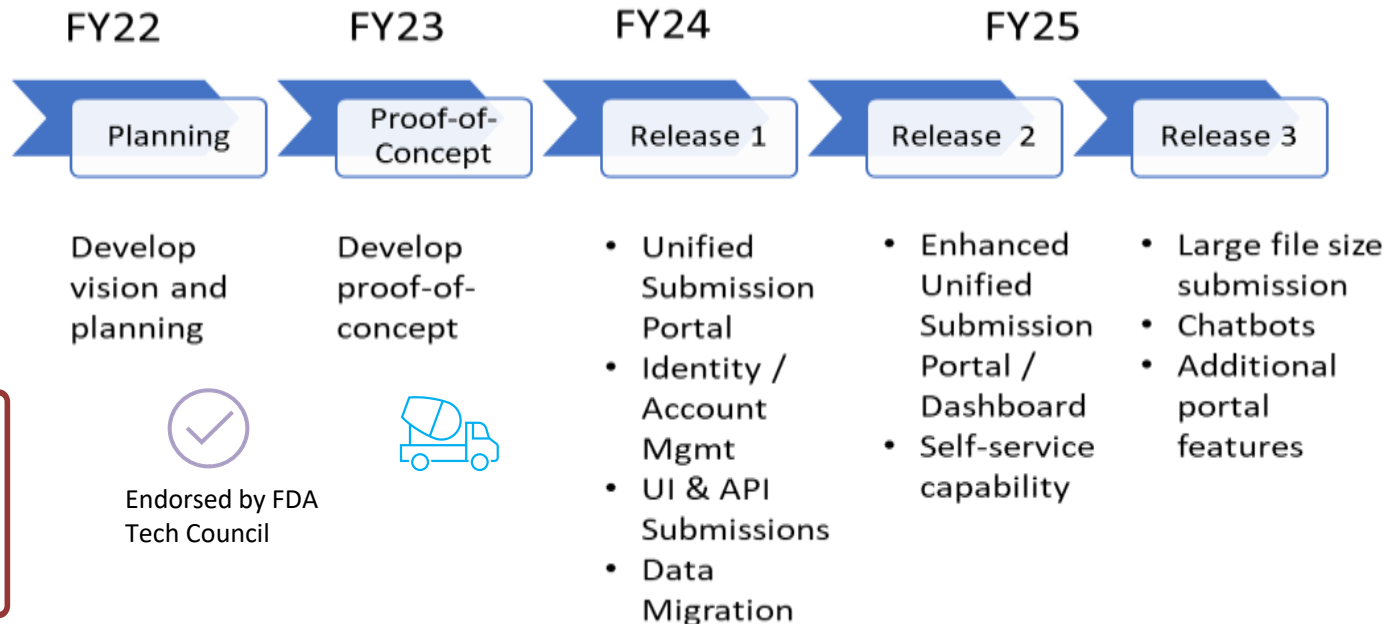
Internal Systems Enhancements

- Internal systems enhancements to support review of DHT-related submissions:
- Updated 1571/356h forms
- Updated FDA systems to support application and file level tracking
- Developed Mercado dashboard for reviewers to easily identify and track submissions containing DHT-generated data and the rate of change of DHT related submissions.

DHT Data Submissions

- FDA has secure cloud technology for processing **large files**
 - However, it is **limited** by current ESG capacities
- DHT summary data comes in high volumes
 - Presently, data above 100GB, is submitted on a **hard drive**
 - This restriction will be **reduced or eliminated** through the ESG modernization
- However, **high-granularity** DHT data could be much larger
 - It may **never** be advisable to submit via ESG

ESG Nextgen Roadmap



- Industry outreach and planning (quarterly basis)
- Develop testing strategy with industry & solicit testers
- Update ESG NextGen website with information, specifications, user guides, FAQs, progress, etc.
- Conduct testing with industry on each release before going live, incorporating lessons learned

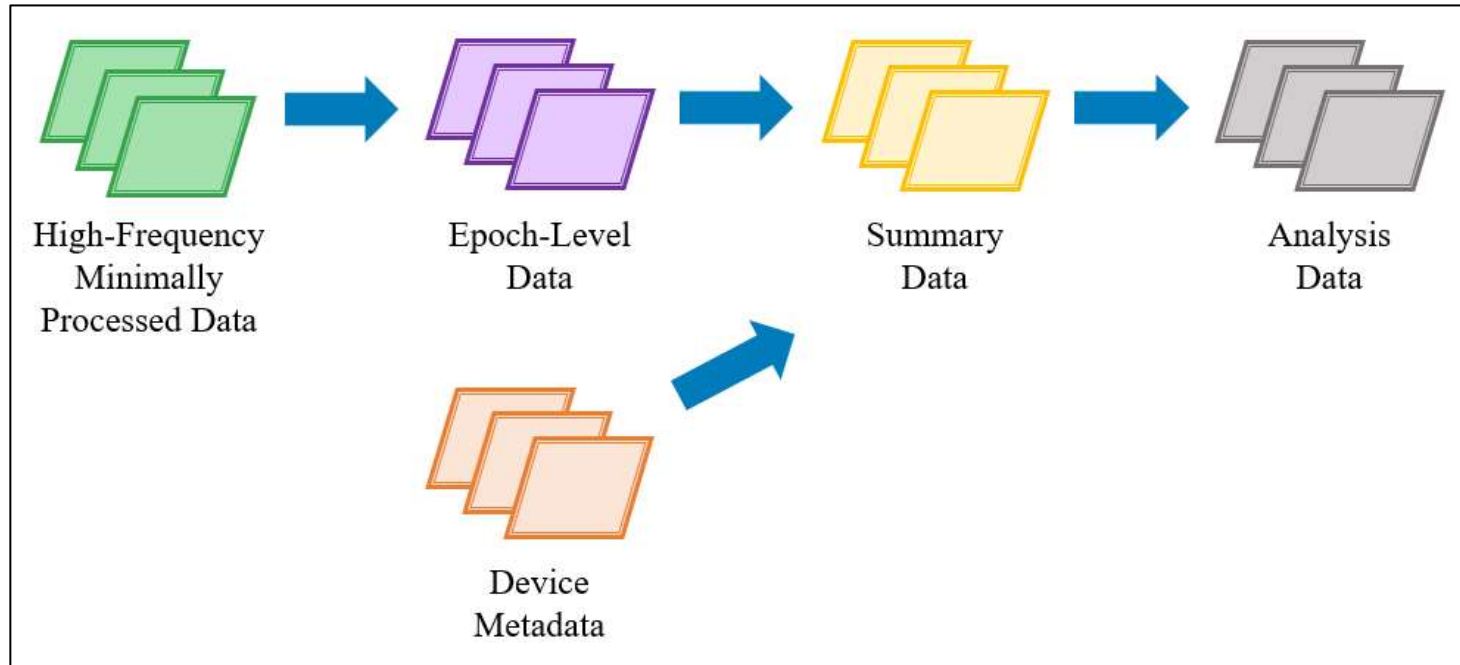


Challenge Question #1

What is the current limit to submission size through the ESG:

- A. 100 MB
- B. 100 GB
- C. \$100
- D. None of the above

DHT Datasets and Submission



HF Data vs Other DHT Data

- High-Frequency (HF) data is **not required** for submission
 - Contains digitized **device data**
 - Can offer valuable **methodological** insights
 - The need is expected to become **significantly reduced** as FDA advances its DHT data submission requirements
- The size of HF data will likely remain beyond ESG limits
 - Other forms of data, such as videos or waveforms, may take **even more space** than continuously recorded tabular data
 - Submitting HF data via ESG would also create unnecessary **records management challenges**

Challenge Question #2

DHT HF data is:

- A. Not required for submission
- B. The largest of the types of DHT data
- C. Digitized data that can offer valuable insights
- D. All of the above
- E. None of the above

DHT Pilot: Study Description

| | |
|-------------------------|----------------------------------------------------------------------------|
| Therapeutic area | Psychiatry |
| Population | ~2,000 adolescents and young adults at risk for developing schizophrenia * |
| Study design | A prospective non-interventional cohort study |
| Study duration | 2 years |
| Cloud platform | precisionFDA |
| Granularity | HF or epoch data |
| Data sources | Smartphone, wearable activity monitors, etc. |
| Data volume | Several TB |



DHT Pilot: Objectives

- Enhance FDA's ability to receive, validate, clean, and analyze external data on a 3rd-party platform
- Explore architectural and business process considerations to work with **HF DHT data**
- Explore methodological considerations for informing future regulatory **guidance** for submitting DHT-generated data

Potential Benefits for DHTs

- Mitigate **ESG bandwidth** constraints
- Provide **real-time** access for sponsors and reviewers
- Enable real-time sampling and **analysis** of HF data
- Support reviewer-sponsor **interaction** on DHT data
- Potential for **other** data-intensive use cases such as RWD

Challenge Question #3

Where is the DHT pilot to be conducted:

- A. Amazon Govcloud
- B. Microsoft Azure
- C. PrecisionFDA
- D. Joe's Garage

Closing Thought

DHTs can add enormous value to drug development and FDA supports the use of DHT-generated data for this purpose. We've made a lot of progress but have more to do.

This is just the beginning.

