PDUFA VII Goals For Digital Health Technologies – A Technical Perspective

Mary Ann Slack
Director
Office of Strategic Programs
CDER | US FDA

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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

FY22	FY23	FY24	FY25	
Planning	Proof-of-Concept	Release 1	Release 2	Release 3
Develop vision and planning	Develop proof-of-concept	• Unified Submission Portal • Identity / Account Mgmt • UI & API Submissions • Data Migration	• Enhanced Unified Submission Portal / Dashboard • Self-service capability	• Large file size submission • Chatbots • Additional portal features

Endorsed by FDA Tech Council

- 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:

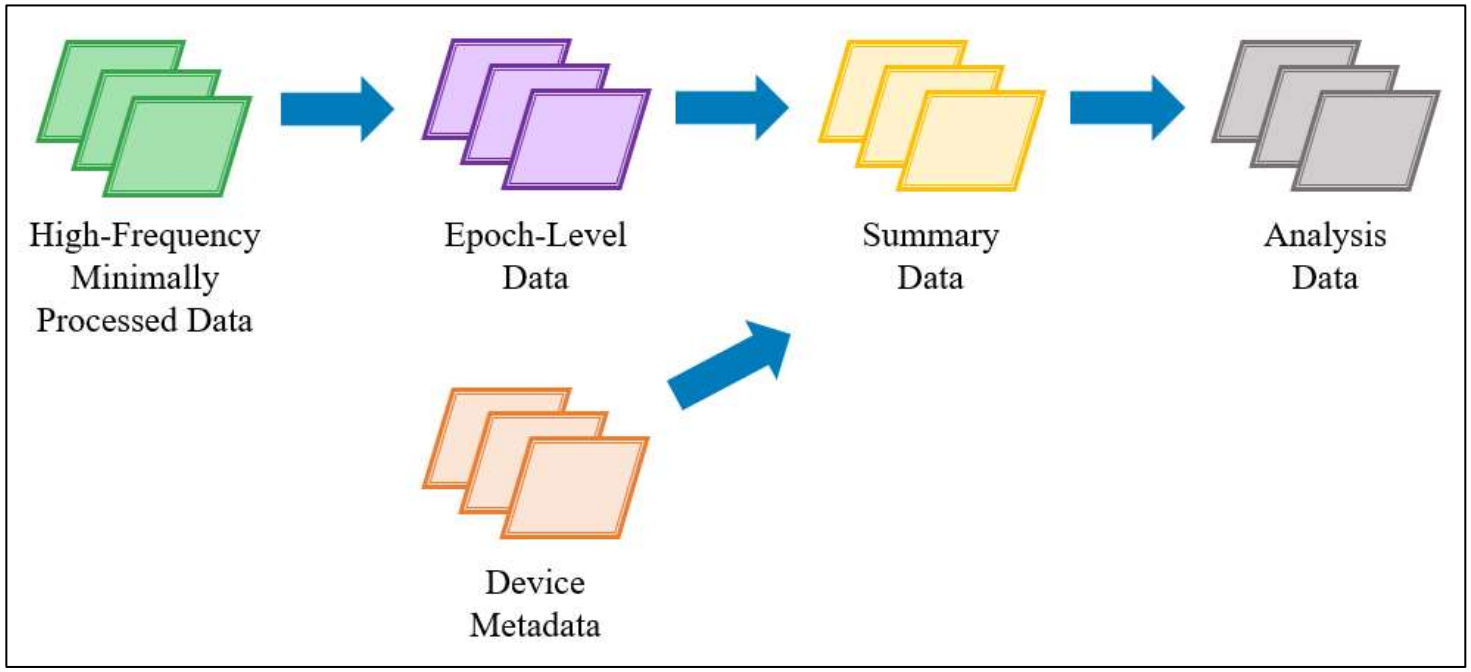
A. 100 MB

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.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