



FDA Form 1571 2023 Updates



Effective March 2023, the FDA updated FDA Form 1571. Information is provided in this document on the two new items (Field 1, Field 12B), as well as a refresher on SNOMED CT.

- **Field 1 Center (CDER or CBER)**
- **Field 12B Digital Health Technology (DHT) data**
- **Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT)**

CDER or CBER

Field 1: Which Center are you submitting to?

CDER for most drug products

*this includes monoclonal antibody therapies

CBER for vaccines, biologics and blood products

*note that several oncology products such as CAR T-cell therapies are biologic-based and go to CBER

Digital Health Technology (DHT) data

Field 12B: Does the submission contain: Digital Health Technology (DHT) data or a proposal to collect DHT data?

If the submission contains DHT data or a proposal to collect DHT data, select 'Yes'.

DHTs are systems that use computing platforms, connectivity, software, and/or sensors, (e.g., activity trackers, mobile medical applications) for remote data acquisition from participants in a clinical investigation. The FDA is starting to track clinical trial and drug application submissions containing DHT-derived data. This will help the FDA understand the changing landscape of DHT utilization, and the trends, challenges, and opportunities for implementation.

FDA currently has a draft guidance out this DHT topic: <https://www.fda.gov/media/155022/download>.

Examples of DHT data:

Yes, this is a Digital Health Technology:

- Using a Fitbit, Apple watch, Actigraph, etc to record health data
- Memory task performed on a smartphone
- Using a continuous glucose monitor device and with analysis and alarm functions
- Spirometer with smart connectivity
- Mobile App where subjects rate their perceived functioning each day
- Medical device to remotely measure sleep parameters while subjects sleep at home

No, this is not a Digital Health Technology:

- Using the EMR to record information about the patient in the trial
- Using a digital camera to record photos of skin lesions
- Communicating with the patient via hospital-based telehealth services

Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT)

SNOMED CT is the most comprehensive clinical healthcare terminology in the world supported by National Library of Medicine (NLM), Center for Disease Control (CDC) and Prevention and the Office of National Coordinator (ONC) for Health Information Technology.

SNOMED CT is the required FDA terminology standard for coding study data indications of IND submissions. For each original submission (including resubmissions to this submission type), provide the SNOMED CT coded disease term (e.g., 38341003 | Hypertensive disorder, systemic arterial (disorder) |) for the indication provided in Field 8A.

How to locate SNOMED CT Information:

To look up the indication's SNOMED CT coded disease term, do the following:

1. Navigate to <http://browser.ihtsdo.org/>.
2. Under Local Extensions, select 'Go Browsing United States edition'.
3. Select 'Search' tab located in the upper left hand of page.
4. Enter the disease term in the search field.
5. Check the box 'Group by concept'.
6. Select the single most appropriate term for the indication.
7. Select the 'Expression' tab located in the upper right hand of page.
8. Copy the entire text that appears under the heading 'Pre-coordinated Expression.'
9. Paste the copied SNOMED CT disease term into Field 8B of Form FDA 1571.
10. For additional indications, use a continuation page and repeat these steps

Resources

FDA Forms:
<https://www.fda.gov/about-fda/reports-manuals-forms/forms>

Contact Us

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