



Form FDA 1571
2023 Updates
 (Revised)



Effective March 2023, the FDA has again updated form FDA1571. 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 Digital Health Technology (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.

FDA currently has a draft guidance out this DHT topic: 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

Examples of what is, and what is not considered 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.

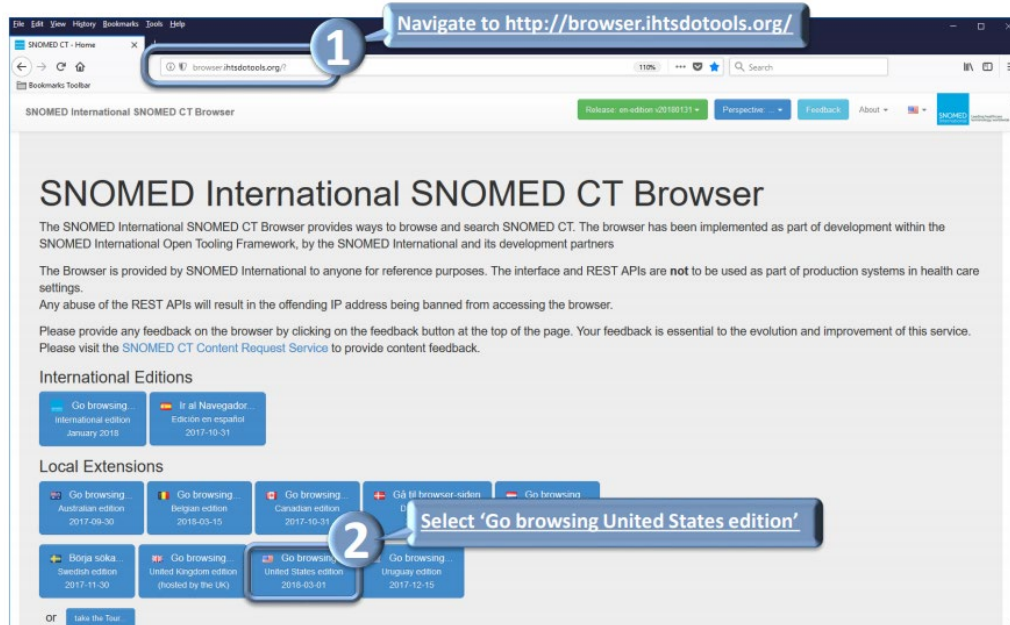
See field 8A and 8B on the form FDA 1571.

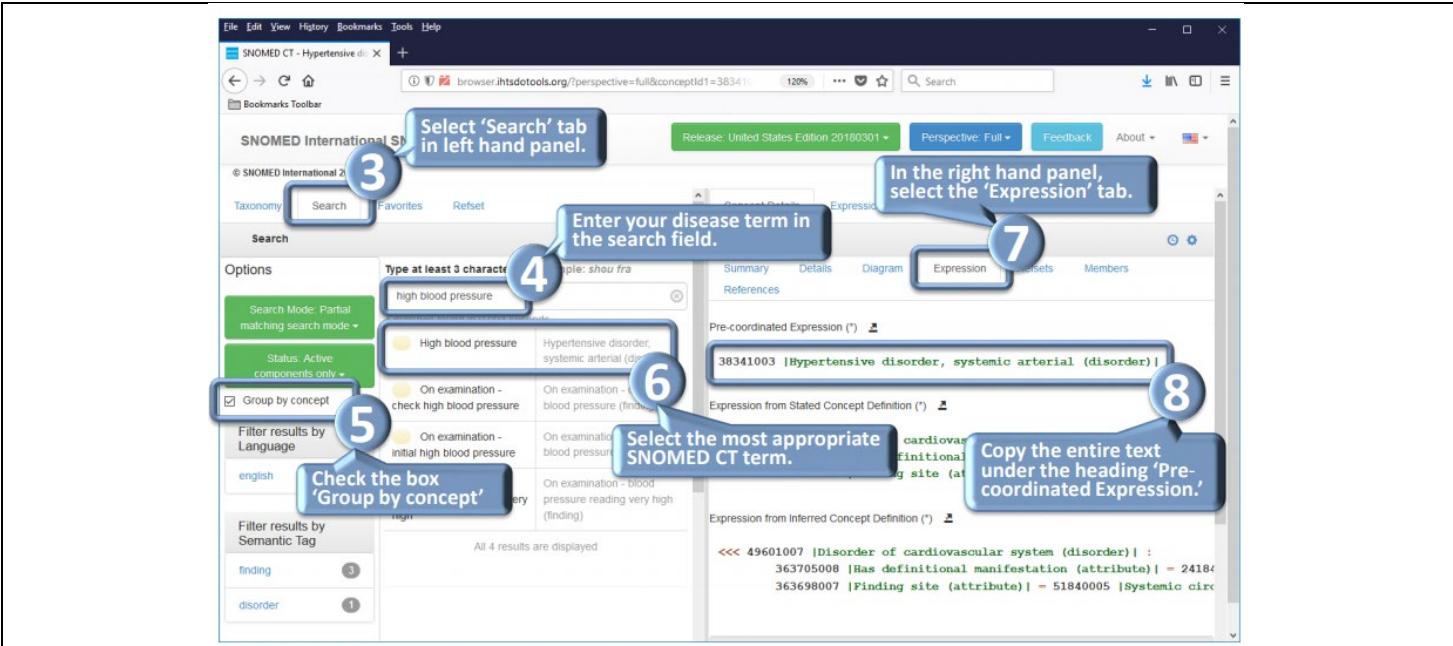
| | |
|---|--|
| 8A. (Proposed) Indication for Use | Is this indication for a rare disease (prevalence <200,000 in U.S.)? <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | Does this product have an FDA Orphan Designation for this indication? <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | If yes, provide the Orphan Designation number for this indication: |
| | Continuation Page for #8 |
| 8B. SNOMED CT Indication Disease Term (<i>Use continuation page for each additional indication and respective coded disease term</i>) | |

How to find SNOMED CT information for your indication

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

1. Navigate to <http://browser.ihtsdotools.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.





Paste the entire text copied including the upright lines from the 'Pre-coordinated Expression' field, in field 8B of the Form 1571.

Example: 38341003 | Hypertensive disorder, systemic arterial (disorder) |

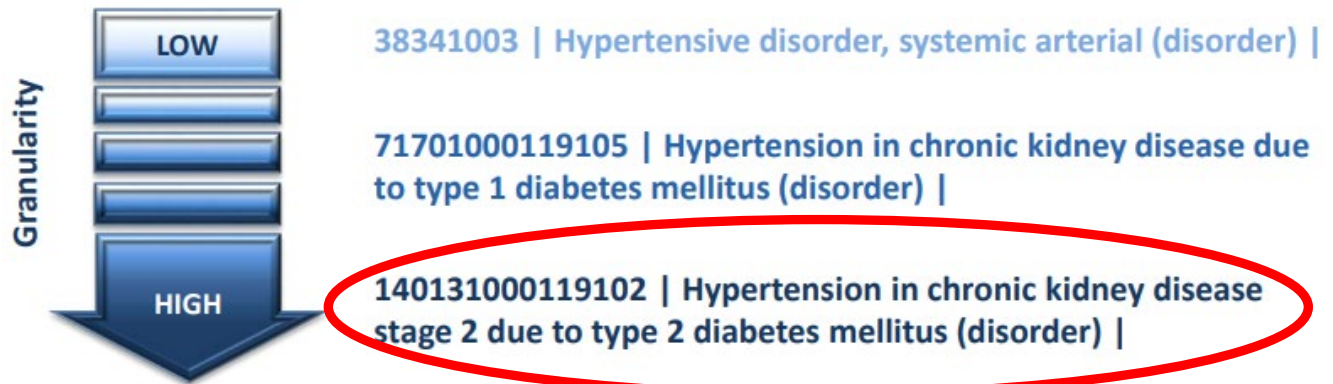
| | |
|--|--|
| 8A. (Proposed) Indication for Use | Is this indication for a rare disease (prevalence <200,000 in U.S.)? <input type="checkbox"/> Yes <input type="checkbox"/> No |
| <div style="border: 1px solid black; height: 40px;"></div> | Does this product have an FDA Orphan Designation for this indication? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, provide the Orphan Designation number for this indication: |
| Continuation Page for #8 | |
| 8B. SNOMED CT Indication Disease Term (Use continuation page for each additional indication and respective coded disease term) | |
| 38341003 Hypertensive disorder, systemic arterial (disorder) | |

Use the "Continuation Page for #8" button to provide additional indications and respective SNOMED CT Codes.

| | |
|--|--|
| 8A. (Proposed) Indication for Use | Is this indication for a rare disease (prevalence <200,000 in U.S.)? <input type="checkbox"/> Yes <input type="checkbox"/> No |
| <div style="border: 1px solid black; height: 40px;"></div> | Does this product have an FDA Orphan Designation for this indication? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, provide the Orphan Designation number for this indication: |
| Continuation Page for #8 | |
| 8B. SNOMED CT Indication Disease Term (Use continuation page for each additional indication and respective coded disease term) | |

FAQs about SNOMED CT

- SNOMED CT terminology can have multiple levels of “granularity”. Some indication disease terms may have low granularity, while some may have high granularity.
- Use the term with the highest granularity possible.



New versions of SNOMED CT US Edition are generally available in March and September of each year. Be sure to check for updated information when submitting additional information or supplement submissions for every new 1571 that goes to the FDA.

<http://browser.ihtsdotools.org>

Resources

[Instructions For Filling Out Form FDA 1571
Investigational New Drug Application](#)

[FDA 1571 Form](#)

Contact Us

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