

DATE: July 26, 2024
TO: Daniel Cline, OMB Desk Officer
FROM: Joella Roland, HRSA Information Collection Clearance Officer

Request: The Health Resources and Services Administration (HRSA) is requesting OMB approval for the following updates to the Stem Cell Therapeutic Outcomes Database (SCTOD) information collection (OMB 0915-0310 expiration date 08/31/2025).

Purpose: The overall purpose of the data collection is to fulfill the Stem Cell Act legislative mandate to establish and maintain a standardized database of allogeneic (related and unrelated donor) marrow and cord blood transplants performed in the United States or using a donor from the United States. This memo seeks approval for several non-substantive corrections to the previously OMB-approved information collection. This memo explains the changes and supporting rationale.

HRSA requests approval to modify several pre-transplant data variables for accuracy. HRSA seeks to correct a data field based on an organization name change, establish a more complete/updated list of response options, and provide clarity for data users. This will help ensure proper data usage and accurate information collection for the C.W. Bill Young Cell Transplantation Program (CWBYCTP). The complete spreadsheet of information collection to support the SCTOD has been updated appropriately.

The changes to the information collection do not change the nature or type of information being collected under 0915-0310 – they represent new or updated response options to existing questions in the information collection system. This aligns with the purposeful design of the information collection system for the SCTOD to streamline changes that we anticipate on a nearly continual basis to maintain currency in the field on behalf of the CWBYCTP as outlined in our last public notice published in the Federal Register Notice in June 2022. A copy of that FRN is attached with highlighted sections (Tab A).

Changes: Table 1 below provides a list of the proposed changes to the information collection instrument, with revisions highlighted in red text:

Table 1: SUMMARY OF CHANGES FOR STEM CELL THERAPEUTIC OUTCOMES DATABASE VARIABLES.

| Current Information Collection Data Element | Current Information Collection Data Element Response Option(s) | Proposed Information Collection Data Element Response Option(s) | Rationale for Information Collection Update |
|---|--|--|---|
| Study Sponsor | BMT CTN, RCI-BMT, PIDTC, USIDNET, COG, PedAL, Other sponsor | BMT CTN, RCI-BMT CIBMTR CRO Services , PIDTC, USIDNET, COG, PedAL, Other sponsor | Capture data accurately - Organization name change |
| Study ID Number | BMT CTN 0301 - Aplastic Anemia, BMT CTN 0601 - Sickle Cell Anemia, BMT CTN 0701 - Follicular Lymphoma... | BMT CTN 0301 - Aplastic Anemia, BMT CTN 0601 - Sickle Cell Anemia, BMT CTN 0701 - Follicular Lymphoma... COG APAL2020SC (PedAL), COG ASCT2031, COG AALL1732, COG AAML1831 <i>Shown above are representative response options from a total of 56 for this data element.</i> | Capture data accurately - Addition of several new clinical studies |
| Name of product | Other name | Betibeglogene autotemcel (Zyntelgo®), Elivaldogene autotemcel (Skysona®), Exagamglogene autotemcel , Other name | Capture data accurately - Addition of several new gene therapy products |
| Glomerular filtration rate (GFR) | _____ mL/min/1.73 ² | _____ mL/min/1.73m ² | Capture data accurately - Correction of unit of measure typo |

The changes are also highlighted in yellow in the “Change Summary” tab in the Excel spreadsheet, “Current SCTOD Information Collections to HRSA 2023-08-10” (Tab B). Once the changes are approved, the information in the tab “Pre-Transplant Information Coll” will be adjusted accordingly.

Time Sensitivity: The SCTOD information collection changes must be completed in a timely manner to help ensure that information is represented accurately. Approval of these changes is requested by September 27, so that HRSA can update its public-facing materials with updated information.

Burden: These changes will not increase the reporting burden.

Attachments:

- Tab A: Published FRN 2022-12225 Highlighted
- Tab B: Current SCTOD Information Collections to HRSA