S1826 Data Submission Tips

Spring 2023 ORP Open Forum

A PHASE III, RANDOMIZED STUDY OF NIVOLUMAB (OPDIVO) PLUS AVD OR BRENTUXIMAB VEDOTIN (ADCETRIS) PLUS AVD IN PATIENTS (AGE >= 12 YEARS) WITH NEWLY DIAGNOSED ADVANCED STAGE CLASSICAL HODGKIN LYMPHOMA

Data is submitted on S1826 via the following 3 applications

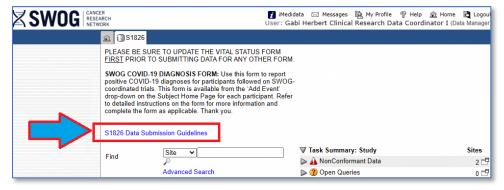
- iMedidata Rave eCRFS and source docs per protocol section 14
- SWOG Specimen Tracking System tissue and blood specimens per protocol section 15
- TRIAD imaging submission per protocol section 15

Tips for resolving expectations

- Always check protocol section 14 for data submission requirements
- You can run a Current Expectation Report any time via the Expectations page on the SWOG CRA Workbench
- Your IPR is based on expectations in the SWOG database, not Rave calendaring
- Carefully read protocol section 15 for specimen submission requirements
 - Note that if a tissue block is not submitted at baseline, multiple slides are required per section 15
 - o If a required specimen cannot be submitted, you must use the 'Notify that Specimen Cannot be Submitted' link in the Specimen Tracking System to resolve the expectation
- If you submitted imaging but still receive an expectation for it, check if the TRIAD imaging report appears in Rave
 - o If so contact LymphomaQuestion@crab.org and we can resolve the expectation
 - o If not contact SWOG1826@irocohio.org to see if there was an issue with the TRIAD submission

S1826 Data Submission Guidelines

- This document addresses frequently asked questions about data submission on \$1826
 - o This doc is to supplement form instructions, NOT to replace them. Please always read form instructions!
- Direct link: https://txwb.crab.org/txwb/CRA MANUAL/Vol1/chapter%2016g S1826%20Data%20Submission%20Guidelines.pdf
- The S1826 Data Submission Guidelines can also be accessed from...
 - SWOG CRA Workbench (CRA Manual, Chapter 16g)
 - ctsu.org (S1826 protocol documents)
 - Rave (S1826 landing page, see screenshot below)



Key Contacts for Data Submission Questions

- LymphomaQuestion@crab.org
 - o Questions related to data submission in Rave, SpecTrack, how to resolve expectations, etc.
 - Reaches all study data coordinators and back-ups
 - Include "S1826" and the patient ID in your inquiry
- ctsucontact@westat.com
 - Questions about Rave access (including Delegation of Tasks Log questions)
- SWOG1826@irocohio.org
 - o Questions about TRIAD image submission

^{**}For further study contact information, please see the S1826 Protocol Contact Information page in the protocolst