HOBIT

2024 Goals Meeting

Friday, January 26, 2:00 pm – 3:00 pm ET

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Agenda

Friday, January 26th, 2024 2:00pm - 3:00pm ET			
Start	**End**	**Item**	**Presenter**
2:00pm	2:05pm	Welcome	Gaylan Rockswold
2:05pm	2:15pm	Enrollment Updates & Enrollment Projections	Byron Gajewski
2:15pm	2:40pm	Plan for Funding and Type 2 Application	Fred Korley
2:40pm	2:45pm	NIH Support	Gretchen Scott
2:45pm	2:55pm	Protocol and MOP Updates ● Enrolling without ICP Monitor ● Vital Status Search ● Hourly Monitoring ● GOSE	Fred Korley Peyton Kline Natalie Fisher Sarah Rockswold
2:55pm	3:00pm	Adjourn	Gaylan Rockswold

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Welcome

Gaylan Rockswold

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Welcome!

- We welcome you and appreciate your attendance
- 2024 will be a pivotal year for HOBIT
- The purpose of our meeting is to inform you of our goals and your critical role in achieving those goals
- Our current enrollment is 110
- Our first interim analysis for efficacy/futility will occur at 116 patients
- Enroll 116 subjects ASAP
- Each enrollment from each site is critical

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Enrollment Updates & Projections

Byron Gajewski

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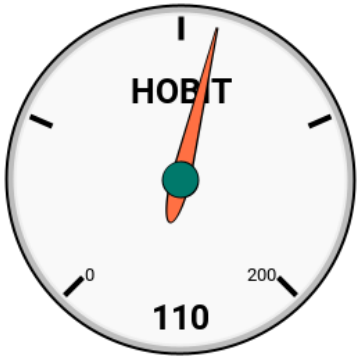
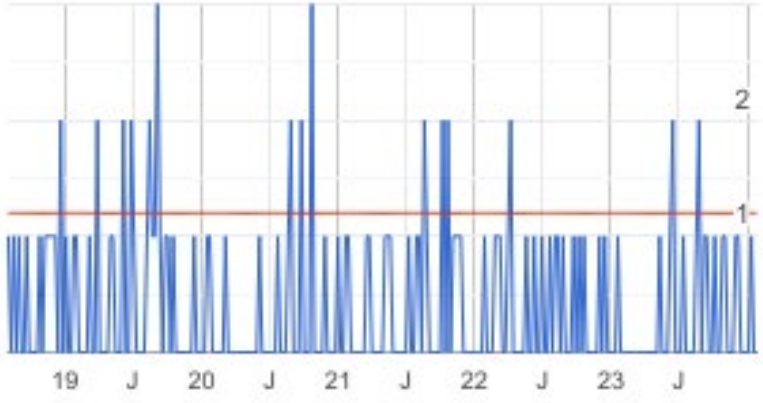
Accrual - tracking





You can always see up to the minute accrual data by clicking the "enrollment dashboard" tile on the siren.network website

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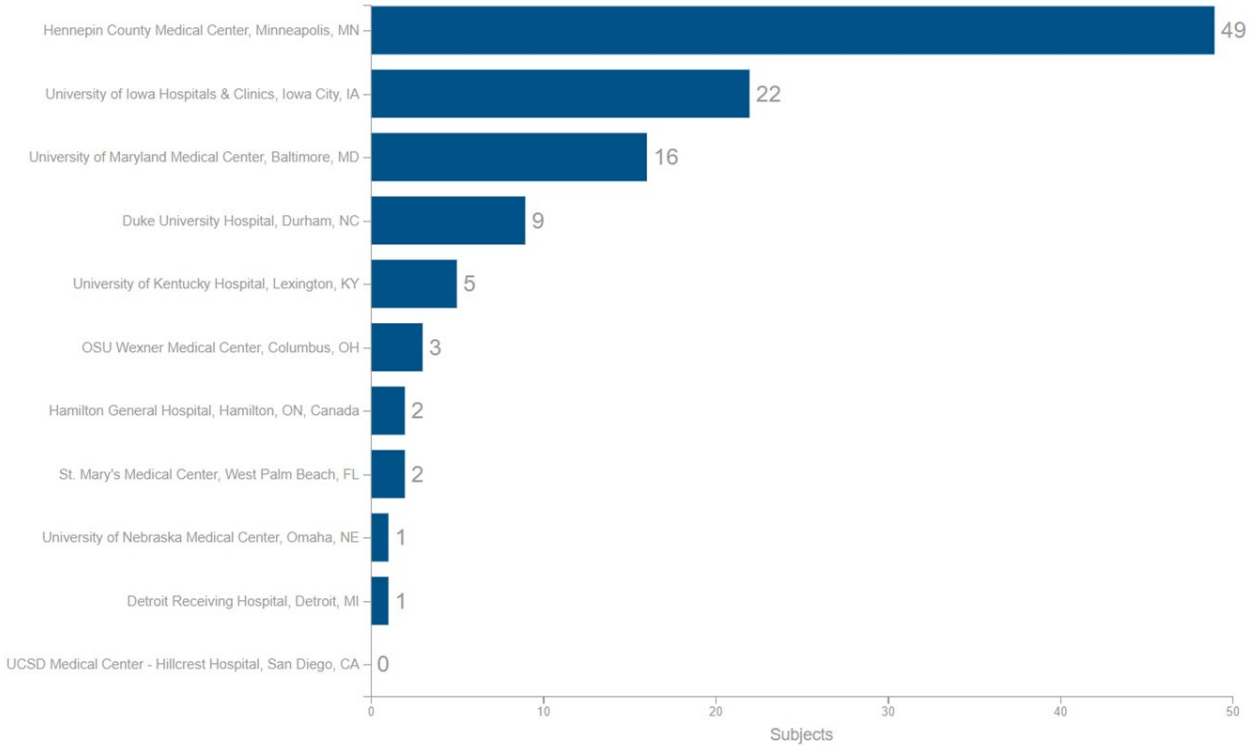
Randomized by Site



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Enrollment Projections

As of 01/09/2024 we have enrolled 110 participants (about 5/quarter)

Bayesian prediction, uses a prior and the current enrollment rate

When will we achieve 116?

- We expect this to be March 23, 2024 with 95% interval from February 6, 2024 to June 12, 2024

When will we achieve 200?

- We expect to reach 200 on April 1, 2027 with 95% interval July 13, 2026 to February 19, 2028

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Enrollment Projections, What If?

We have 8 sites that have enrolled at least 2 participants. The top 2 sites currently enroll 8.8 and 4.1 participants per year, respectively

What if, these 2 sites stay at the same rate, but the other 6 sites each enroll 4/year i.e. one every three months?

When will we achieve 116?

- March 8, 2024

When will we achieve 200?

- June 6, 2026

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Plans for Funding and Type 2 Application

Fred Korley

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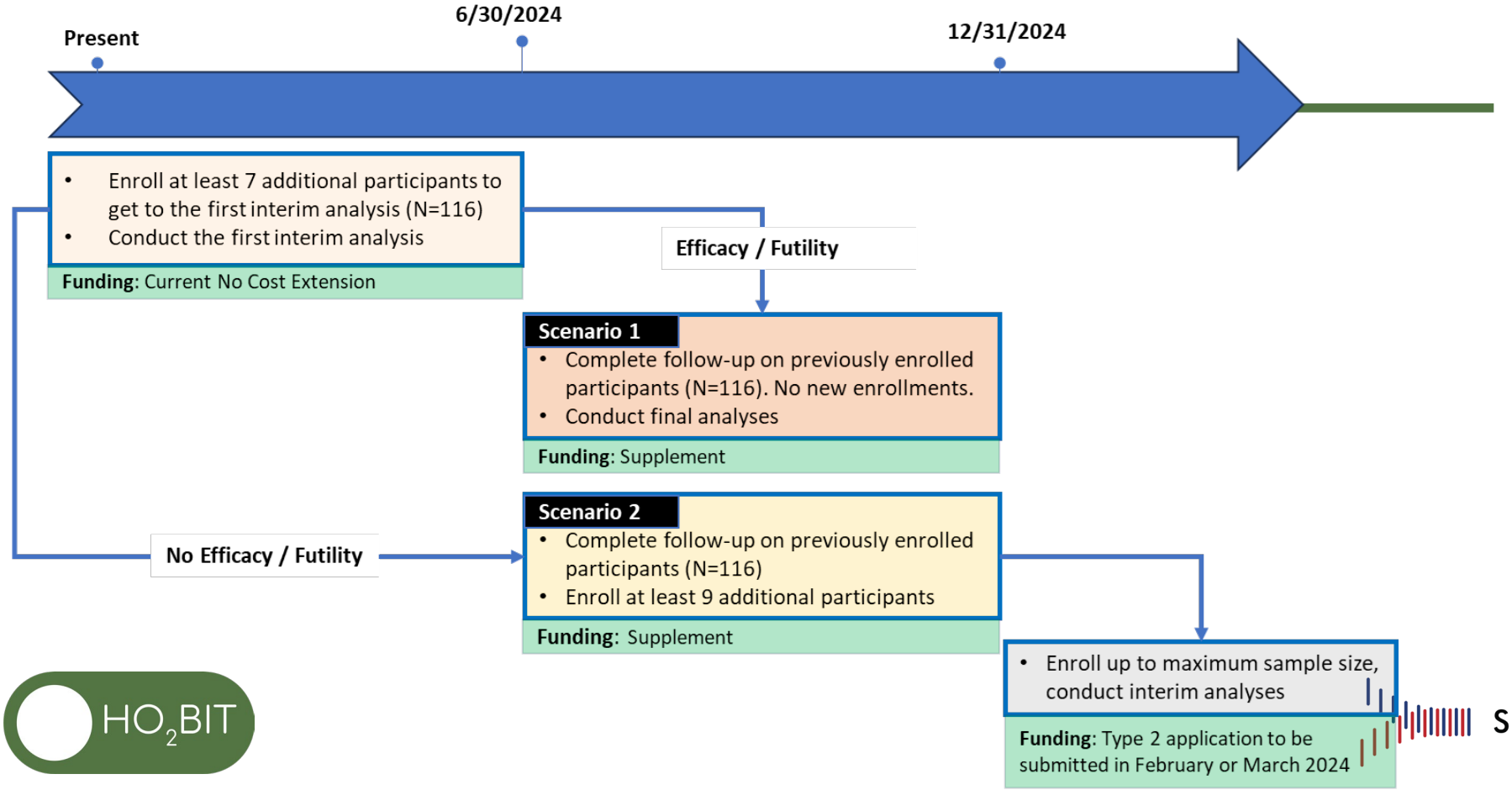
Present
6/30/2024
12/31/2024
Enroll at least 7 additional participants to get to the first interim analysis (N=116)
Conduct the first interim analysis
Funding: Current No Cost Extension
Efficacy / Futility
Scenario 1
Complete follow-up on previously enrolled participants (N=116). No new enrollments.
Conduct final analyses
Funding: Supplement
No Efficacy / Futility
Scenario 2
Complete follow-up on previously enrolled participants (N=116)
Enroll at least 9 additional participants
Funding: Supplement
Enroll up to maximum sample size, conduct interim analyses
Funding: Type 2 application to be submitted in February or March 2024
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NIH Support

Gretchen Scott

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Protocol and MOP Updates

Fred Korley, Peyton Kline, Natalie Fisher, Sarah Rockswold

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Enrolling Subjects without an ICP Monitor

Data Collection Guidelines Update:

If the HOBIT participant is approved and enrolled without an ICP monitor, sites should document the following statement in the general comments on F101 - [Subject enrolled without ICP, approved by PI hotline on MM/DD/YYYY]. Additionally, sites should add an issues record to the Issues table in WebDCU with a similar statement.

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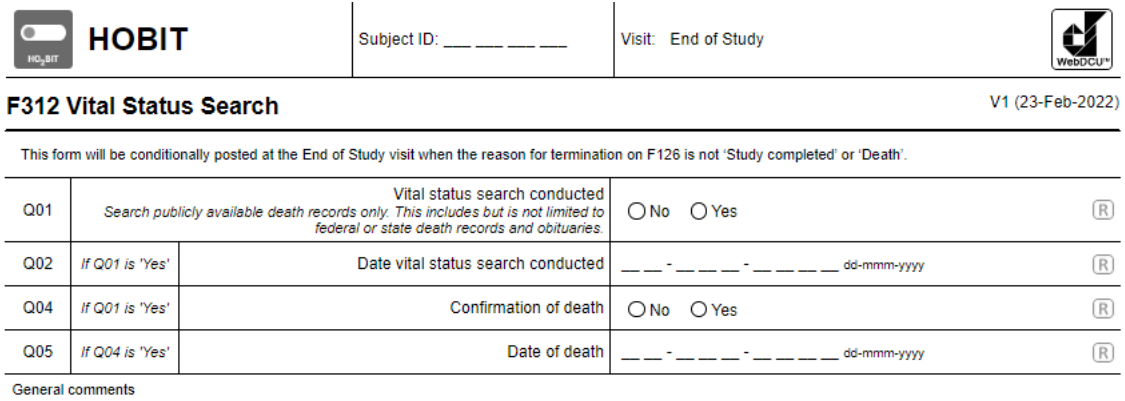
F312 Vital Status Search

To minimize bias due to missing outcome data, at minimum, we will strive to obtain vital status/death data from all enrolled participants. This includes those who are deemed “lost to follow-up” and those who withdraw from the study. For these participants, we ask enrolling sites to review publicly available data sources such as obituaries, or other public records of vital status/death. These reviews should occur after the date of the 6-month visit. Findings from this search should be documented on the F312 Vital Status Search form in WebDCU. Only deaths occurring within the 6-month window should be recorded.



HOBIT | Subject ID: __ __ __ __ | Visit: End of Study | WebDCU

F312 Vital Status Search V1 (23-Feb-2022)

This form will be conditionally posted at the End of Study visit when the reason for termination on F126 is not 'Study completed' or 'Death'.

Q01		Vital status search conducted *Search publicly available death records only. This includes but is not limited to federal or state death records and obituaries.*	◯ No ◯ Yes	R
Q02	*If Q01 is 'Yes'*	Date vital status search conducted	__ __ - __ __ __ - __ __ __ __ dd-mmm-yyyy	R
Q04	*If Q01 is 'Yes'*	Confirmation of death	◯ No ◯ Yes	R
Q05	*If Q04 is 'Yes'*	Date of death	__ __ - __ __ __ - __ __ __ __ dd-mmm-yyyy	R

General comments

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F501 Hourly Monitoring

ICPs will be recorded on ICU flowcharts every 15 minutes until the ICP normalizes (ICP<22 mmHg). Using the ICU flowsheet as the source document, the study team will document whether the ICP during any given clock hour was >22 mmHg for over 20 minutes (episode of intracranial hypertension) in WebDCU.

If the ICP was greater than 22 mmHg for over 20 minutes, the highest ICP recorded during that hour will also be documented. If the highest ICP during any hour is ≤22 mmHg, the highest ICP variable will be left blank for that hour.

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GOSE

If a site cannot complete an assessment within the respective windows (30 days (± 7 days) post-injury, 90 days post-injury (± 14 days), and 180 days (± 21 days) post-injury) sites must ask HOBIT leadership for an extension to contact the subject out of window by emailing: hobit-milestone@umich.edu. If it appears that the participant and caretaker may not be reached within their outcome window, the primary study coordinator and/or GOSE outcome assessor should reach out to Dr. Sarah Rockswold for guidance.

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Adjourn

Gaylan Rockswold

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