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DATA MANAGEMENT CENTER

NEWSLINE

frontier science foundation

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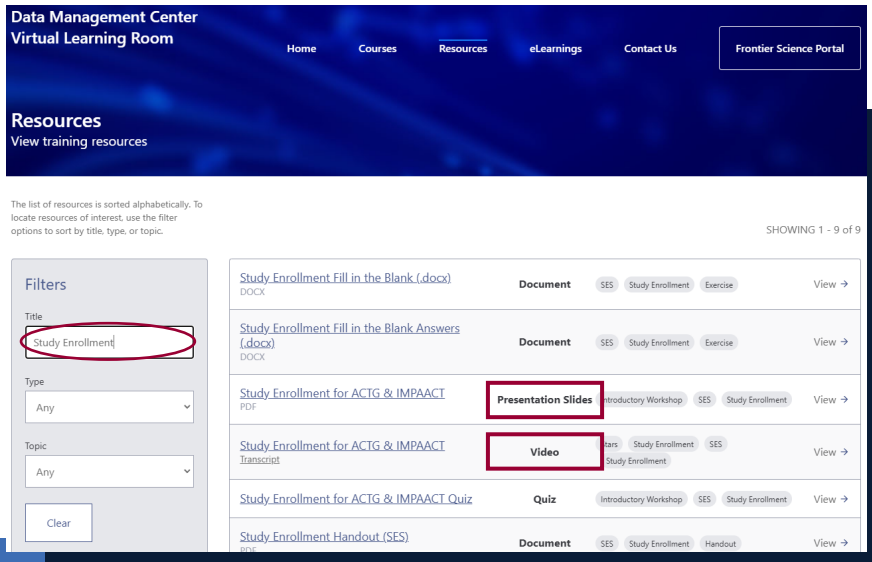
Study Enrollment Training Resources

As a reminder, ACTG and IMPAACT studies already using the Study Enrollment System will continue using the system. All new studies for ACTG and IMPAACT will be developed in Stars. The DMC Virtual Learning Room offers on-demand training for site users. Please refer to the following pages for an overview of the enrollment process associated with each system.



Study Enrollment System Basics

Site Established

- After site receives DAIDS site approval, receive PID list from DMC via e-mail
- PID list sent to CRS coordinator

Site Approved to Enroll

- Must be Protocol Registered AND granted Site Readiness approval by the ACTG or IMPAACT Operations office in order to begin screening/enrolling participants
- Contact the study Clinical Trial Specialist (CTS) or Clinical Research Manager (CRM) with any questions pertaining to the approval status
- SID list is physically mailed to the Pharmacist of Record (PoR) after approval is granted

Note: The pharmacist cannot dispense treatment without the SID list. Prior to scheduling the first participant for enrollment, the site must confirm that the pharmacist has received the SID list. If they have not received the SID list prior to the first participant being enrolled, the PoR should contact the Randomization Department requesting the SID list. The Randomization Department will then send the list directly to the PoR via encrypted email.

Assigning PIDs

- If the participant was previously enrolled onto an ACTG/IMPAACT study, use that PID. Otherwise, site assigns the next available PID from the PID List

Screening

- Once the participant has signed the Informed Consent, use the Study Enrollment System (SES) to obtain a screening number. From the Study dropdown list, select one of the following (or study-specific checklist, if used):
  - → "S1001 ACTG Screening Checklist" for ACTG studies
  - → "PS2001 IMPAACT Screening Checklist" for IMPAACT studies
- After submitting the completed checklist, a screening number will be assigned if the submission was successful

Enrollment

- Enter the screening number and PID assigned to the participant in the appropriate eligibility checklist questions
- After submitting the completed checklist, a SID number will be assigned if the enrollment was successful
- Provide the SID number to the pharmacist to dispense treatment

Does Not Enroll

- Complete screening failure electronic case report form(s) (eCRFs) in Rave

PID: Unique participant ID assigned to a participant prior to enrollment.
Example: 1234567f
If the participant was previously enrolled to an ACTG or IMPAACT study, use that PID when enrolling.

PID list: List of PIDs given to a site in preparation for enrollment. Sites assign PIDs to potential participants.

SID: Study ID. Obtained from the SES at time of successful enrollment. Participant receives a SID at each step. Corresponds to a treatment (on treatment studies).
Example: A1234 5678c

SID list: Mapping of SIDs to treatment regimens. Pharmacist uses this list to prepare a treatment regimen for a newly enrolled PID.

Screening number: Number assigned by the SES to a participant after successful completion of screening checklist.

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Screening and Enrollment via Stars

Site Established

- After site receives DAIDS site approval, receive PID list from DMC via e-mail
- PID list sent to CRS coordinator

Site Approved to Enroll

- Must be granted approval by the ACTG or IMPAACT Operations office in order to begin screening/enrolling participants.
- Contact the study Clinical Trial Specialist (CTS) or Clinical Research Manager (CRM) with any questions pertaining to the approval status
- Once a site receives approval to begin screening/enrolling participants onto a treatment study, the study will immediately appear in the Treatment Assignments module for the site pharmacists

Assigning PIDs

- If the participant was previously enrolled onto an ACTG/IMPAACT study, use that PID. Otherwise, site assigns the next available PID from the PID List

Screening

- Once the participant has signed the Informed Consent, use the Stars Register/Randomize module to obtain a screening number.
  - → From the Checklist dropdown list, select **Screening** *(there is no need to select the specific screening checklist from the dropdown)*.
  - → If Screening is not used, or is on hold for your site, it will not be listed.
- After submitting the completed checklist, a screening number will be assigned if the submission was successful.

Enrollment

- Enter the screening number and PID assigned to the participant
- SID number will be assigned if the enrollment was successful; Treatment studies instruct user to provide PID and SID to pharmacist

Does Not Enroll

- Complete screening failure electronic case report form(s) (eCRFs) in Rave

PID: Unique participant ID assigned to a participant prior to enrollment.
Example: 1234567f
If the participant was previously enrolled to an ACTG or IMPAACT study, use that PID when enrolling.

PID list: List of PIDs given to a site in preparation for enrollment. Sites assign PIDs to potential participants.

SID: Study ID. Obtained from Stars at time of successful enrollment. Participant receives a SID at each step. Corresponds to a treatment (on treatment studies).
Example: A1234 5678c

Screening number: Number assigned to a participant in Stars, after successful completion of screening checklist.

Treatment Assignments Module: The Treatment Assignments module is used by approved site pharmacists to determine the study agent or treatment regimen assigned to participants. This module is not displayed for users with other project roles.

SpecimenRepository

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Specimens Added to the Specimen Repository Website

The Specimen Repository Website is a data visualization tool with the goal of making specimens available to investigators for new and innovative research. The website, located at www.specimenrepository.org, is a collaborative project among the ACTG, IMPAACT, and HVTN networks.

Additional ACTG studies now available:

A5371 – A Single-Arm, Open-Label, Pilot Study of Semaglutide for Non-Alcoholic Fatty Liver Disease (NAFLD), a Metabolic Syndrome with Insulin Resistance, Increased Hepatic Lipids, and Increased Cardiovascular Disease Risk (The SLIM LIVER Study)

A5381 – Observational Cohort to Assess Therapeutic Efficacy and Emergence of HIV Drug Resistance Following Initiation of Tenofovir-Lamivudine-Dolutegravir (TLD) for First- or Second-Line ART or with Rifampicin-Containing TB Treatment (The Hakim Study)

A5404 – SARS-CoV-2 Immune Responses after COVID-19 Therapy and Subsequent Vaccine

Additional IMPAACT studies now available:

P1112 – Open-Label, Dose-Escalating, Phase I Study to Determine Safety and Pharmacokinetic Parameters of Subcutaneous (SC) VRC01, VRC01LS, and VRC07-523LS, Potent Anti-HIV Neutralizing Monoclonal Antibodies, in HIV-1-Exposed Infants

2008 – Phase I/II Multisite, Randomized, Controlled Study of Monoclonal Antibody VRC01 with Combination Antiretroviral Therapy to Promote Clearance of HIV-1-Infected Cells in Infants

2015 – The IMPAACT 2015 study, titled *"Evaluation of HIV-1 Reservoirs in the Central Nervous System of Perinatally Infected Youth and Young Adults with Cognitive Impairment on Suppressive ART,"* focused on assessing CSF HIV-1 reservoirs in perinatally HIV-1-infected youth and young adults aged 13-30. The primary objective was to determine the prevalence of quantifiable cell-free HIV-1 RNA in CSF. Secondary objectives included assessing the prevalence of detectable HIV-1 DNA in CSF cell pellets and evaluating associations between CSF HIV-1 reservoirs and concentrations of inflammatory and neuronal injury biomarkers in both CSF and plasma. They found that evidence of persistent HIV-DNA in CSF suggests that the CNS should be considered in treatment and cure studies and has implications for cognitive health in this population. These important findings from this study are detailed in a recent publication (Wagner et al., 2024).

Citation:

Wagner TA, Tierney C, Huang S, Nichols S, Malee KM, Montañez NA, Coletti A, Spiegel HML, Krotje C, Bone F, Wilkins M, Abuogi L, Purswani M, Bearden A, Wiznia A, Agwu A, Chadwick EG, Richman D, Gandhi M, Mehta P, Macatangay B, Spector SA, Spudich S, Persaud D, Chahroudi A; IMPAACT 2015 Protocol Team. Prevalence of detectable HIV-DNA and HIV-RNA in cerebrospinal fluid of youth with perinatal HIV and impaired cognition on antiretroviral therapy. AIDS. 2024 Aug 1;38(10):1494-1504. doi: 10.1097/QAD.0000000000003937. Epub 2024 Jun 4. PMID: 38814693; PMCID: PMC11239098. Retrieved from https://pubmed.ncbi.nlm.nih.gov/38814693/

Signing eCRFs in Rave—Quick Reference for Investigators

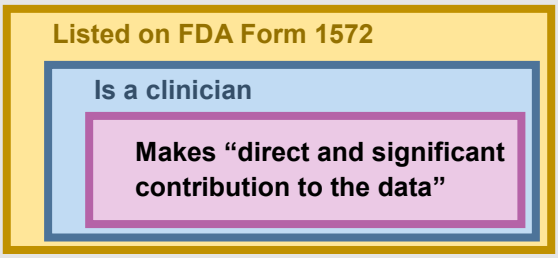
Electronic signatures are required to comply with the International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) guidelines. These guidelines indicate that an investigator "should ensure the accuracy, completeness, legibility, and timeliness of the data reported to the sponsor in the CRFs and in all required reports" (4.9.1) and that it should be documented "that the investigator or authorized member of the investigator's staff confirms the observations recorded" (8.3.14).

Remember, your electronic signature indicates that you verify the information entered on the eCRF is correct. Only sign an eCRF when you are satisfied that this is true.*

Who Is Authorized to Sign an eCRF?

To be authorized to sign eCRFs, investigators must meet three criteria:

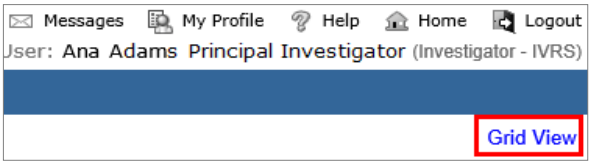
- Must be listed on FDA Form 1572 for the site (sections 1 and 6) or DAIDS Investigator of Record agreement.
- Must be a clinician, such as a medical doctor or nurse.**
- Must make a "direct and significant contribution to the data," which means he or she has direct responsibility for treating or evaluating

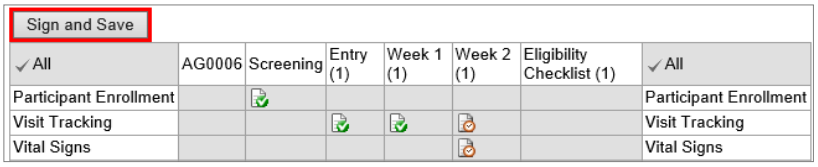


How Do I Sign a Batch of eCRFs? (Recommended Approach)

The DMC will request signatures at specific protocol milestones, generally corresponding to a data lock or freeze. However, investigators can sign eCRFs at any time based on their internal procedures. You can apply signatures in a batch for each participant; you cannot apply them on the site level. The DMC will notify sites when a study milestone is met and the investigator is required to sign. However, investigators are encouraged to sign throughout the course of the study as part of their internal QA/QC and data review procedures, keeping in mind that clinical site monitors or the DMC may query data requiring data changes and re-signature at any time while the study is ongoing.

In *Rave*, navigate to the subject level. There, you can sign for all eCRFs collected at one visit, one eCRF collected at multiple visits, or all eCRFs at once.

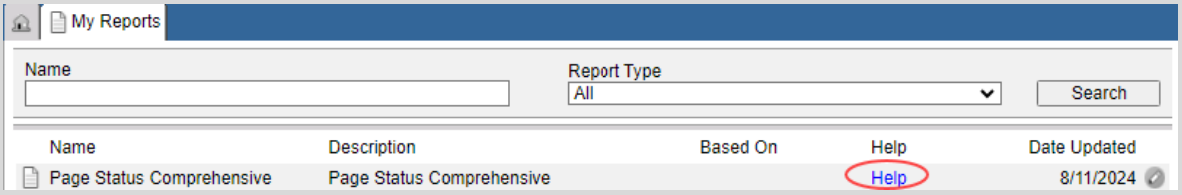




In the upper right-hand corner, select the *Grid View* link. In Grid View, you may select a folder (visit) by clicking a column header, select an eCRF by clicking a row header, or select "All." Selected cells will be highlighted. Next, click *Sign and Save* and enter your credentials.

You can also sign all eCRFs at once for a participant in Calendar View. Under the table of visits and dates, you will see "For all applicable Forms sign below" and a *Sign and Save* button. Click this button and enter your credentials.

Rave's **Comprehensive Page Status Report** is a study data monitoring report that provides a summary of the current overall statuses of all CRFs within a specified study, site group, subject, folder, and/or form. The report is available to users with the Clinical Research Coordinator - IVRS role and provides a summary of all sites or subjects that have the greatest number of pages in need of signature, entry lock, etc. This report will still display signature status, even if the user does not have signature permissions. See the Help document available in the Reporter module within Rave for additional information.



** You can sign eCRFs that have outstanding queries or non-conformant data, but modifying the data to correct the error will require a new electronic signature.*

*** Limited exceptions for certain studies (i.e. behavioral studies) where there may not be a medical doctor on site.*

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IN MEMORIAM—ANDREW M. MILLER

We are deeply saddened by the passing of Andrew M. Miller, our dear friend and colleague. Andrew made significant contributions to Frontier Science Foundation during his 25 year career, traveled extensively in support of LDMS training initiatives, and was dedicated to helping others. Andrew was a talented, published photographer and avid sports fan, recognized for his dedication to local sports teams. Many of his photos were featured in newspapers and magazines, as well as a magazine cover and calendar. He will be fondly remembered by all who had the pleasure to know him.

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Employee Spotlight: Martha Gutierrez - eTMF Document Specialist

Where are you from?

Born in Los Angeles, CA and both parents are from Medellin Colombia.

What is your background?

With over 20 years of experience, I have fulfilled several roles in support of clinical research, including Research Coordinator, Project Manager, and Regulatory Specialist.

What is your education?

I am currently studying to get my BBA in International Business and Global Management.

How long have you worked at Frontier Science?

2 years as of April 2024.

What does a typical day for you at Frontier Science look like?

As an eTMF Document Specialist, I review the eTMFs for any ACTG or IMPAACT study requiring review. I work closely with the PDMs, LDMs, and other team members daily to address specific documents uploaded to our TMF, ensuring everything is properly managed and up to date.

What is your favorite part about working at Frontier Science?

One of my favorite parts about working at Frontier Science has been collaborating with my team and colleagues from different departments. Their expertise has greatly contributed to my learning and deepened my understanding of the data management field and its crucial role in clinical research as a whole.

What was your greatest work-related accomplishment of the past year?

Attending last year's Veeva Summit was an incredible learning experience. Collecting valuable data and having the opportunity to present and share that knowledge and insight was a meaningful achievement.

What is the best part of your job?

The best part of my job is knowing I'm part of an organization whose mission is not only dedicated to finding solutions and treatments that could potentially change the course of HIV/AIDS, but also improve the quality of life for individuals, families, and communities across the globe.

What are your passions/interests outside of the workplace?

When I am not working, I'm either cooking, supporting my boys on the sidelines at their soccer matches or out to dinner with friends.

What would people be surprised to know about you?

I'm a great cook! It's a rewarding process that brings family together and allows me to experiment with different techniques and flavors. Cooking for family and others makes me happy and there's nothing quite like seeing someone enjoy a meal you've prepared.

What was the last book you read?

The last book I read was Atlas Obscura: Wild Life: An Explorer's Guide to the World's Living Wonders. Reading this book made me feel as though I was on a journey all over the world discovering unknown species and their unique ecosystems. It's truly a great read.

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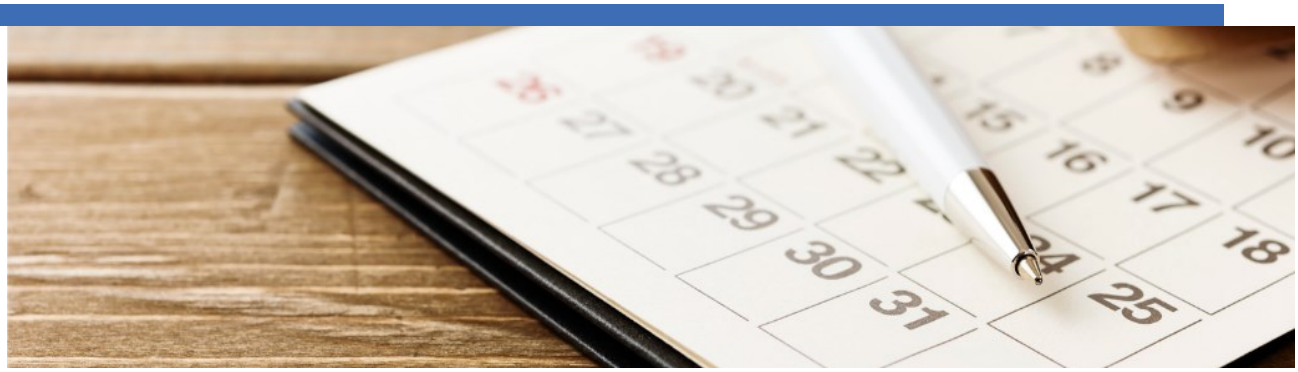

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January 2025

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November 2025

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December 2025

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MARK YOUR CALENDARS

Virtual DMC Introductory Workshops

- January 28-30
- April 29 - May 1
- August 26-29
- October 28-30

Monthly LDMS Webinar Schedule

www.ldms.org/training/schedule

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ACTG & IMPAACT

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