



IMPAACT NETWORK ANCILLARY STUDIES & INVESTIGATIONS

JUNE 2018

ANCILLARY STUDIES

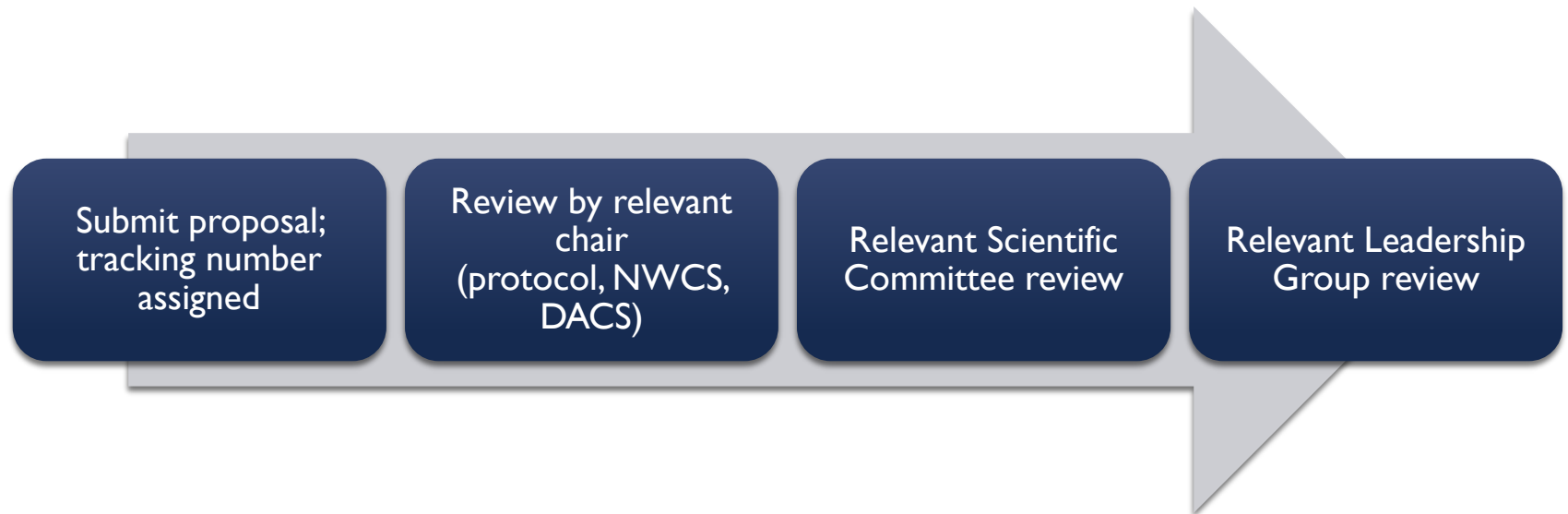
Data Request (DR)	Data Analysis Concept Sheet (DACS)	New Works Concept Sheet (NWCS)
<p>A proposed investigation for which <u>existing data</u> from an IMPAACT (or Pediatric AIDS Clinical Trials Group [PACTG]) study are being requested for analyses to be performed <u>without Statistical and Data Analysis Center (SDAC) statistician IMPAACT funding.</u></p>	<p>A proposed investigation involving analysis of <u>existing data</u> from an IMPAACT (or PACTG) study <u>to be undertaken by SDAC with IMPAACT funding.</u></p>	<p>A proposed investigation involving use of <u>existing biological specimens</u> from an IMPAACT (or PACTG) study that <u>may or may not require IMPAACT funding and may or may not involve analysis work by SDAC</u></p>

ANCILLARY STUDIES

- If the IMPAACT Network has not designated a study as concluded or openly available for use by investigators outside of the protocol team, the objectives of the proposed investigation should not overlap with the objectives stated in the study protocol or with secondary analyses defined by the protocol team after receipt of the final analysis report.
- For DACSs and DRs: The objectives should also not overlap with objectives specified in an approved IMPAACT DACS or NWCS that is not yet completed.
- For NWCSs: The objectives should also not overlap with objectives in an approved IMPAACT NWCS that is not yet completed.

ANCILLARY STUDIES REVIEW PROCESS

- Study proposals using the appropriate template form should be submitted to impaact.capsubmissions@fstrf.org
- The Operations Center will then assign a number to the proposal and initiate the IMPAACT review process



IMPAACT STUDY PROPOSALS

Capsule, DACS, NWCS,
and DR Templates are
available at:

<https://impaactnetwork.org/resources/study-proposals.htm>

The screenshot shows the top navigation of the IMPAACT website. The logo is "IMPAACT International Maternal Pediatric Adolescent AIDS Clinical Trials Network". The navigation menu includes: Home, About Us, Directory, Contact, Site Map, Search here... (with a magnifying glass icon), Research Areas, Studies, Community, Publications, News, and Resources. Below the navigation is a banner for the "2018 Annual Meeting" featuring a photograph of the US Capitol building with red and purple flowers in the foreground. To the right of the photo, the text reads: "MEETINGS ANNUAL MEETING The 2018 IMPAACT Network Annual Meeting is right around the corner! The meeting will be held 16-19 June in Washington, D.C. SEE MORE".

Our mission



Our mission is to significantly decrease incident HIV and HIV-associated infections and to decrease mortality and morbidity due to HIV and HIV-associated infections and co-morbidities among infants, children, adolescents and pregnant/postpartum women.

Read the IMPAACT Network Update Regarding Dolutegravir in Pregnant Women with HIV

Directory



IMPAACT Study Status Table



Submit Study Proposals



IMPAACT STUDY PROPOSALS

Capsule, DACS, NWCS,
and DR Templates are
available at:
<https://impaactnetwork.org/resources/study-proposals.htm>

The screenshot shows the IMPAACT website interface. At the top, the IMPAACT logo is displayed with the tagline "International Maternal Pediatric Adolescent AIDS Clinical Trials Network". Navigation links include Home, About Us, Directory, Contact, Site Map, and a search bar. A secondary menu contains Research Areas, Studies, Community, Publications, News, and Resources. The main content area features a banner for the "2018 Annual Meeting" with a background image of the US Capitol building. A central white box titled "Templates" lists four items: IMPAACT Capsule (CAP), Data Request, New Works Analysis Concept Sheet (NWCS), and Data Analysis Concept Sheet (DACS) Submissions. Below this list, a paragraph states that all completed submissions should be sent to the IMPAACT Operations Center for consideration, using the email address impaact.capsubmissions@fstrf.org. A green banner at the bottom of the main content area reads "Read the IMPAACT Network Update Regarding Dolutegravir in Pregnant Women with HIV". At the bottom of the page, there are three blue buttons: "Directory" with a group of people icon, "IMPAACT Study Status Table" with a microscope icon, and "Submit Study Proposals" with a globe icon. A blue arrow points to the "Submit Study Proposals" button.

Home | About Us | Directory | Contact | Site Map | Search here...

Research Areas | Studies | Community | Publications | News | Resources

2018 Annual Meeting

MEETINGS
ANNUAL MEETING

Templates

- **IMPAACT Capsule (CAP)**
- **Data Request**
- **New Works Analysis Concept Sheet (NWCS)**
- **Data Analysis Concept Sheet (DACS) Submissions**

All completed submissions should be sent to the IMPAACT Operations Center for consideration by the IMPAACT network using this email address:
impaact.capsubmissions@fstrf.org. Upon receipt, the Operations Center will confirm receipt of your submission.

Read the IMPAACT Network Update Regarding Dolutegravir in Pregnant Women with HIV

Directory | IMPAACT Study Status Table | **Submit Study Proposals**

SPECIMEN AND DATA USE AGREEMENT (SDUA)

An SDUA is required for the following:

- Any export of human genomic data
- Any NWCS
- Export of data under a DR or DACS
- Shipment of specimens and/or data sets for an approved IMPAACT protocol if the activity has not been described in the protocol or DAIDS Clinical Trials Agreement
- Export of data from multiple studies for a meta-analysis or other grouped analysis, even if not developed as a formal DR or DACS

ACTG/IMPAACT SPECIMEN REPOSITORY

Information on available biological specimens for concluded studies can be accessed on the interactive ACTG/IMPAACT Specimen Repository website:
www.specimenrepository.org

SpecimenRepository

Help / FAQ | Site Feedback

Home | Search the Repositories | Submit a Proposal | About us | Contact us

**Specimens for research,
collected for large global
clinical trials networks**

SEARCH THE REPOSITORIES

The specimen repositories are a collaboration between the ACTG and IMPAACT clinical trial networks to make the large body of specimens collected for HIV research available to investigators.

ACTG (The AIDS Clinical Trials Group) and IMPAACT (The International Maternal Pediatric Adolescent AIDS Clinical Trials) are two large global efforts studying HIV and related infections.

The specimens stored at the repositories were initially collected for specific studies that have concluded, and are now available to investigators conducting new research.

Using this website

You can use the interactive search tool on this website to learn about the types of specimens available at the repositories. After completing a search, you can see the number of specimens and unique participants available, information about the studies for which they were collected, and what research was published for those studies. The search tool will also provide you with a report that lists your specimens of interest. You can then use this report to help write your research proposal to the network.

What's In the repositories?

Network	ACTG	IMPAACT
Specimens	2775053	428387
Protocols	226	21
Types of specimens	21	10
Cryopreserved PBMCs	699378	151628
Plasma	1571674	264955
Serum	453054	10517

ACTG AIDS CLINICAL TRIALS GROUP | **IMPAACT**

IMPAACT STUDIES



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Re Studies | Community | Publications | News | Resources

2018 Annual Meeting

P1025 (10039): Perinatal Core Protocol

Study Status	Study Restriction
Closed to Follow Up	United States

What is P1025?

P1025 is a prospective observational cohort study that provides a framework for collection and evaluation of data and collection of repository specimens from HIV-infected pregnant and postpartum women and their infants. The study is designed to assess maternal and infant safety, and the effectiveness of new and existing interventions prescribed for prevention of mother-to-child transmission (MTCT) of HIV and/or women's health.

Study Documents:

- **P1025 Protocol V4 (31 Dec 2008) with CM #1, CM #2, CM #3, CM #4, CM#5, and LoA#1 -24 May 2013**

Sites where the study is implemented:

CRS ID	Site Name	City	Country
5083	Rush University Cook County Hospital Chicago NICHD CRS	Chicago	United States of America

IMPAACT MANUAL OF PROCEDURES

Further details on DACS, DRs, NWCS, capsules, and concept sheet development and review processes are available in the IMPAACT Network Manual of Procedures (MOP)

<https://impaactnetwork.org/resources/policies-procedures.htm>

- Section 9: Protocol Development and Modifications
 - Capsule and Concept Sheet development and review
- Section 15: Ancillary Studies and Investigations
- Section 19: Publications Requirements and Procedures