Specimen Repository Website

Marlene Cooper, M.S.
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?

<table>
<thead>
<tr>
<th></th>
<th>ACTG</th>
<th>IMPAACT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specimens</td>
<td>1328464</td>
<td>304780</td>
</tr>
<tr>
<td>Protocols</td>
<td>195</td>
<td>17</td>
</tr>
<tr>
<td>Types of specimens</td>
<td>19</td>
<td>9</td>
</tr>
<tr>
<td>Cryopreserved PBMCs</td>
<td>260576</td>
<td>97932</td>
</tr>
<tr>
<td>Plasma</td>
<td>881257</td>
<td>155289</td>
</tr>
<tr>
<td>Serum</td>
<td>146890</td>
<td>10734</td>
</tr>
</tbody>
</table>
Project Goals

• Increase investigator access to ACTG/IMPAACT repository specimens, specifically for non-network investigators

• Encourage use of repository specimens for new scientific proposals

• Improve upon the existing static request form to provide an on-demand, interactive search tool
Key Considerations

• Public website – no login credentials required

• Designed for investigators unfamiliar with the research of the ACTG/IMPAACT networks

• Protect confidentiality of data and ensure proper use based on participant consent for use of stored specimens
Key Considerations

• Include specimens from approved, concluded studies

• Data available from NIAID (BRI) and NICHD (Fisher) Repositories
Timeline

• Funded by DAIDS via the ACTG/IMPAACT networks in August 2014

• Nine month development process with several intermediate deliverables for network input and review
  • Design elements
  • Wireframes
  • Beta version

• Production announcement on April 29, 2015
Collaborations

- FSTRF developed the database and search tool
- Emerson Media provided website design
- FHI360 provided key study data elements and publications for IMPAACT studies
- SSS provided key study data elements and publications for ACTG studies
- ACTG/IMPAACT leadership and DAIDS project officers provided input throughout
The Website

- Interactive tool for viewing aggregate specimen counts based on search criteria
- Displays information about studies in search results
- Provides information and links about the NWCS process

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<tr>
<th>Specimens</th>
<th>ACTG</th>
<th>IMPAACT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cryopreserved PBMCs</td>
<td>269,976</td>
<td>979,282</td>
</tr>
<tr>
<td>Plasma</td>
<td>88,925</td>
<td>195,289</td>
</tr>
<tr>
<td>Serum</td>
<td>146,090</td>
<td>1,073,400</td>
</tr>
</tbody>
</table>

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User Workflow

Step 1
Search

Step 2
Review results

Step 3
Prepare NWCS
Step 1: Search

- **Two ways to search**
  - By study number
  - Define search criteria

- **Types of criteria**
  - Specimen characteristics
  - Study characteristics
  - Participant characteristics
Step 1: Search (Example)

- Viable PBMCs
- Female participants
- Baseline samples
Step 2: Review Results

- Results grouped by study and material type
- Shows number of unique participants and specimens
- Hover over study for details about it

<table>
<thead>
<tr>
<th>Study</th>
<th>Material Type</th>
<th>Unique Participants</th>
<th>Specimens</th>
</tr>
</thead>
<tbody>
<tr>
<td>IMPAACT P1053</td>
<td>PBMC viable (Add Citrate Dextrose)</td>
<td>2</td>
<td>4</td>
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<tr>
<td>IMPAACT P1053</td>
<td>PBMC viable (EDTA)</td>
<td>3</td>
<td>9</td>
</tr>
<tr>
<td>IMPAACT P1034</td>
<td>PBMC viable (Add Citrate Dextrose)</td>
<td>10</td>
<td>44</td>
</tr>
<tr>
<td>IMPAACT P1034</td>
<td>PBMC viable (EDTA)</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>IMPAACT 390</td>
<td>PBMC viable (Add Citrate Dextrose)</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>IMPAACT 390</td>
<td>PBMC viable (EDTA)</td>
<td>19</td>
<td>158</td>
</tr>
<tr>
<td>IMPAACT 382</td>
<td>PBMC viable (Add Citrate Dextrose)</td>
<td>17</td>
<td>33</td>
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<tr>
<td>IMPAACT 382</td>
<td>PBMC viable (EDTA)</td>
<td>8</td>
<td>28</td>
</tr>
<tr>
<td>IMPAACT 381</td>
<td>PBMC viable (Add Citrate Dextrose)</td>
<td>58</td>
<td>293</td>
</tr>
<tr>
<td>IMPAACT 381</td>
<td>PBMC viable (EDTA)</td>
<td>15</td>
<td>38</td>
</tr>
</tbody>
</table>

Total: 109 studies 1 Material Types  4,668 Participants  18,315 Specimens
Details for a study

- Objectives
- Regimen
- Study Location
- Link to Schedule of Events (PDF)
- Links to Published Articles

381: Establishment and Maintenance of Long-Term Undetectable plasma hiv-1 rna: correlation with immunologic reconstitution and viral dynamics

Objectives: To determine if, controlling for baseline viral load, there is a positive correlation between the baseline immunologic status and the virologic and immunologic response to HAART at 1, 2, and 3 years after initiation of treatment.

Regimen: HAART, including either protease inhibitor or EFV

<table>
<thead>
<tr>
<th>Study Location</th>
<th>US</th>
</tr>
</thead>
<tbody>
<tr>
<td>Schedule of Events</td>
<td>The SOE may be downloaded here [PDF format]</td>
</tr>
<tr>
<td>Journal articles</td>
<td></td>
</tr>
</tbody>
</table>

Immune reconstitution and predictors of virologic failure in adolescents infected through risk behaviors and initiating HAART: week 60 results from the PACTG 381 cohort [PubMed ID: 16545007]

Rudy BJ, Lindsey JC, Flynn PM, Bosch NJ, Wilson CM, Hughes ME, Douglas SD. Pediatric AIDS Clinical Trials Group 381 Study Team

AIDS Res Hum Retroviruses 2006 Vol. 22 (3) 213-21

Virologic and immunologic outcomes after 24 weeks in HIV-1 infected adolescents on highly active antiretroviral therapy [PubMed ID: 15216481]

Flynn PM, Rudy BJ, Douglas SD, Lathey J, Spector SA, Martinez J, Sillo M, Beber M, Friedman L, D’Angelo L, McNamara J, Hodge J, Hughes MD, Lindsey JC. Pediatric AIDS Clinical Trials Group 381 Study Team

JID 2004 Vol. 190 (2) 271-9
Step 2: Review Results

• Three ways to save results
  • Print
  • Download PDF
  • Save link

• Links to search results will reflect current data since the specimen database is refreshed weekly
Step 3: Prepare NWCS

- Website provides brief explanation of the NWCS process
- Links to network specific webpages to walk the user through the submission process
- FAQ page provides additional information
Website Usage

• Over 1,000 unique visitors in first month

• Users from over 50 different countries
Feedback

- The website supports basic searches including CD4 counts and HIV viral load
- Other clinical data searches not currently supported
  - Quality of life questionnaire data
  - Treatment exposure
  - Pregnant or breast feeding
- Contact Us link provides mechanism to request additional assistance for more complex queries
Feedback

• 14 requests for assistance with complex queries
• 9 in preparation for IMPAACT Early Career Investigator Award submissions
• Will use feedback and investigator requests to drive new development in the future if funds become available
Thank You

- ACTG and SSS
- IMPAACT and FHI360
- NIAID/DAIDS
- NICHD
- Biomedical Research Institute (BRI)
- Fisher BioServices
- Emerson Media