IMPAAACT 2013
Welcome!

Phase I Placebo-Controlled Study of the Infectivity, Safety and Immunogenicity of a Single Dose of a Recombinant Live-Attenuated Respiratory Syncytial Virus Vaccine, D46/NS2/N/∆M2-2-HindIII, Delivered as Nose Drops to RSV-Seronegative Infants 6 to 24 Months of Age
Protocol team members at the training

- Betsy McFarland, Chair
- Ruth Karron, Vice Chair
- Ulla Buchholz, PhD
- Peter Collins, PhD
- Betty Schappell, JHU SC
- Jocelyn San Mateo, JHU SC
- Lynette Purdue, Prot. Pharm.
- Vivian Rexroad, Site-based pharm.
- Paul Harding, IMPAACT Lab Tech
- Bhavin Thumar, JHU Lab
- Devasana Gnanashanmugam, Med. Officer
- Emily Barr, IMPAACT Field Rep
- Ben Johnston, Data Manager
- Scott Watson, CRA, Westat
- Charlotte Perlowski, CTS
- Jen Libous, CTS
IMPAACT 2013 sites (n = 13)

Previously trained sites
1. 4001 Lurie Children’s Hosp. Chicago
2. 4601 Univ California San Diego
3. 5013 Jacobi Med. Ctr.
4. 5030 Emory Univ.
5. 5040 SUNY Stony Brook
6. 5048 Univ Southern California
7. 5052 Univ of Colorado Denver
8. 5083 Rush Univ. Cook County Hosp.
9. 5112 UCLA School of Med
10. 6501 St Jude/UTHSC
11. 31779 Johns Hopkins CIR

New sites
• 3801 Baylor College of Med/TCH
• 5011 Boston Med. Ctr.
Collaboration

- IMPAACT
- JHU CIR
- LID, NIAID, NIH
Timeline of RSV live attenuated vaccine studies

• 2013: IMPAACT P1114
• 2014: IMPAACT 2000
• 2016: IMPAACT 2011, 2012
• 2017: IMPAACT 2013, IMPAACT TBN (Cap 530)
• 2018: Phase 1b – expanded, simplified study
## Update on 2011/2012/2013

<table>
<thead>
<tr>
<th>Version 1.0 to sites</th>
<th>1st Enrollment</th>
<th>Accrual*</th>
<th>Comment</th>
</tr>
</thead>
</table>
| 2011 (LID ΔM2-2 1030s ) | May 5, 2016 | July 2016 | 33 | Closed to accrual
Achieved target enrollment
Analysis pending |
| 2012 (LID cp ΔM2-2) | Aug 17, 2016 | October 2016 | 17^ | Closed to accrual
Interim analysis: vaccine will not meet at least one of the desired characteristics |
| 2013 (RSV/NS2/N/ΔM2-2-AclI ) | Feb 27, 2017 | April 2017 | 33 projected | Projected to complete enrollment in June based prior experience. |

& Enrolled 30 in July and August 2016, 3 more in Sept/Oct.  
^ Enrolled 17 in October 2016
Welcome to the world of live attenuated RSV vaccine trials
Who doesn’t want to help develop an RSV vaccine??
BUT: these studies are different
What’s going to be different:

• Recruitment outside your HIV program
  – Approach to enroll ratio is **high**
  – Work to establish relationships with other clinics
• Vaccine preparation critical/complex
  – Special supplies
• Sample collection critical/complex/time sensitive
  – in clinic processing
• Daily assessments
  – Weekend work
  – On call for events
• Specifically defined “Solicited” adverse events
• Study pause/stopped for lower respiratory illness
  – Assessment at site must be reliable!
Purpose of training

• Once you get on, this protocol is like a fast train - its hard to get off!
• Training and preparation so you’ll be ready when you get on