State of the IMPAACT Network
June 8, 2011

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Specific Aims

1. Develop and evaluate safe, cost effective approaches to interrupt mother-to-child transmission (MTCT)

2. Evaluate treatments for HIV-infected children, adolescents, and pregnant women, including treatment and prevention of co-infections and co-morbidities

3. Evaluate vaccines for prevention of MTCT and sexual transmission among adolescents, and for therapeutic use
Purpose of Meeting

• Review recent findings and new potential interventions relevant to the IMPAACT scientific agenda
• Review, update, prioritize, and obtain input and feedback on the scientific agenda and Network operational/financial issues
• Plan and strategize for the structure and scientific scope of the future network
• Training
Accomplishments To Date

• From Feb 16, 2010 through Feb 15, 2011, there were 3659 participants on study having enrolled 2041 women, children and adolescents [556 into interventional trials internationally and 409 in the US].

• 47 papers were published and 36 abstracts presented at natl/intl meetings

• Final enrollment and analysis IMPAACT’s 3 largest interventional trials involving 3200 mother-infant pairs and several hundred infants were completed (P1060, HPTN/IMPAACT 046, HPTN/IMPAACT 040)
Major Study Accomplishments Past Year

- **P1060** demonstrated that by week 24 treatment failure was significantly higher in NVP exposed and unexposed infants receiving NVP based vs PI based HAART.

- **HPTN 046** showed that extending daily infant nevirapine (NVP) from 6 weeks to 6 months lowered the risk of HIV transmission through breastfeeding at age 6 months.

- **HPTN040/P1043** showed that neonatal post-exposure prophylaxis with a 2 or 3 ARV drug regimen is superior to ZDV alone for the prevention of intrapartum transmission among infants born to women not receiving ARVs before labor.

- **P1096** HPIV3 vaccine study enrolled in 6 months.

- **P1077** HS, BF and FF are all open for enrollment.
International Sites
Number of Subjects on Interventional Studies
By Month From June 2010 Through May 2011

- June 2010: 2,868
- July 2010: 2,793
- August 2010: 2,692
- September 2010: 2,549
- October 2010: 2,433
- November 2010: 2,318
- December 2010: 2,113
- January 2011: 1,930
- February 2011: 1,672
- March 2011: 1,516
- April 2011: 1,183
- May 2011: 1,073
Domestic Sites
Number of Subjects on Interventional Studies
By Month From June 2010 Through May 2011

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<th>Month</th>
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Present and Future Protocol Plans

- The network has 27 protocols open to enrollment, 9 protocols closed to accrual and 11 protocols in development.

- Currently there are 3,801 participants to be enrolled excluding PROMISE and P1084s (1,510 at international sites and 2,291 at domestic sites which includes 1,829 on P1025 and P1074).

- PROMISE HS, BF, FF and P1084s will enroll 9,000 participants at domestic and international sites.
Six new interventional protocols are planned to open by September 1, 2011 (P1090, P1078, P1092, P1091, START and AERAS 402) requiring a total of 2,595 participants to be enrolled excluding PROMISE and P1084s (2,385 at international sites and 210 at domestic sites).
Priority Protocols for Enrollment

- P1077 HS, BF, and FF (PROMISE)
- P1063 Safety of atorvastatin for PI associated high Chol
- P1072 Safety and immunogenicity of rotavirus vaccine
- P1073 Study of IRIS in infants and children starting HAART
- P1076 Impact of alendronate on BMD
- P1079 PK of artemisinin within context of ART
- P1080 Psychiatric and ARV medication interactions
- P1083 PK Kaletra using weight based dosing guidelines
- P1091 Pneumococcal vaccine to HIV+ pregnant women
- P1094 Evaluation of 3TC monotherapy in virologic failure
- P1097 Safety/PK of Raltegravir in neonates
IMPAACT now needs to plan for the structure and scope of the scientific agenda for the future with an eye towards building an infectious disease center network.
Priorities of Future Peds/Maternal Health Network

- Prevention of HIV acquisition
- Vaccines of high priority to these populations
- PK, safety of new drugs and formulations
- Co-infections, co-morbidities, and ART consequences
- Cure and/or functional cure
Develop a cohesive research agenda in these priority areas with overarching goals and benchmarks.