Meeting Recommendations

Need for positive control reference reagents:

- **sCD4-IgG** — **Current price ~$1,000/mg**
  1 gm = 2,000 1 ml aliquots
  $1M

- **HIV-1 positive plasmas**
- **TriMab**

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Meeting Recommendations

Develop a standard multiclade panel of Tier 1 reference strains:

- **MN (B)**
- **IIIB (B)**
- **SF162 (B)**
- **Bal (B)**
- **Bx08 (B)**
- **BZ167 (B)**
- **SS1196 (B)**
- **W61D-TCLA (B)**
- **MS208 (A)**
- **92RW020 (A)**
- **MW965 (C)**
- **92BR025 (C)**
- **HIV-0012466-2 (C)**

Characterize their neutralization phenotypes with V3 and CD4i MAbs, (also HIV-1-positive sera, broadly neutralizing MAbs)

Meeting Recommendations

Need for parallel neutralization assays:

- **PV assays in genetically engineered cells lines using Luc reporter gene (e.g., TZM-bl, U87.CD4.CXCR4.CCR5)**
- **PBMC assay**
- **Plaque assay**
- **Cell-cell transfer assays**

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Assay Requirements

- Sensitive, quantitative, reproducible, high throughput and have correlative value
- Optimized and validated to meet GCLP requirements for human clinical trials
- Reagents need to be standardized and traceable
- Transferable to multiple labs – requires a rigorous program of standardized proficiency testing to assure assay equivalency across labs

Meeting Recommendations

Need to achieve inter-laboratory equivalency in the PBMC assay:

- **No efforts to do this in the past**
- **Reference strains?**

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Meeting Recommendations

Exploratory assays that detect "other" antiviral antibodies:

- **Macrophage FcR assays (Moog)**
- **Antibody-dependent cell-mediated virus inhibition (ADCVI) (Forthal)**
- **ADCC (Robert-Guroff, Ferrari, others)**
- **Complement (Trkola, others)**
- **Other?**