October 1-2, 2013: Global Clinical Research Summit

Workshop: **Data Safety Monitoring Board (DSMB) Training by Harvard MRCT Center**

Session A:

8.30-9.00 Asian Perspectives regarding History and Responsibilities of DSMBs (Local Speaker and Joe/Barbara)

- History of DSMB in Korea and Asia
- Challenges associated with DSMB monitoring
- Rational and purpose of DSMBs (Joe/Barbara) (8 slides)

9.00-10.00 DSMB Membership and Responsibilities (Joe/Barbara) (25 slides)

- Where DSMB fit in organizational flow
- Composition of DSMBs in Asia
- What members need to know and do (and need to know not to do)
    - Conflict of interest
    - Indemnification
    - Roles and responsibilities of the Chairman of a DSMB
    - Roles and responsibilities of the statistician member of a DSMB
- Roles: review protocol design, assess safety assessment, ensure trial integrity, assess efficacy and futility; make recommendations
- Understanding interim results
- Evaluation of study conduct
- Recruitment and study progress
- The DSMB charter

10.00-10.15 Break

10.15-11.00 Guidance for monitoring clinical trials (Joe/Barbara plus 1 local speaker) (16 slides)

- Meetings: structure and schedule
- Blinding (who is blinded, unblinded)
- Recommendations DSMBs can make
    - Modifying the protocol
    - Stopping a trial
- Communication of DSMB recommendations
- Regulatory issues (Korea)

11.00-11.15 Monitoring for safety (Joe/Barbara) (7 slides)

- How to evaluate safety data – what is important, what is likely spurious
- SAE individual case reports
- Aggregate tables
- Quality of safety reports

11.15-12.00 Monitoring for efficacy (Joe/Barbara) (30 slides) • Issues with multiple "looks" • Methods • Controlling for error rates • Operational issues • Bias • Methods for stopping for efficacy • Limitations of current methods
12.00-13.00 Lunch
13.00-14.00 Monitoring for futility (Joe/Barbara) (30 slides) • Definition of futility • Data used • Metrics for low probability / conditional power • Case study
Note: Role plays were deleted from the agenda

Session B:

14.00-14.15 Multi-regional clinical trials (Joe/Barbara) (10 slides) • Concept • Examples • Issues that can occur with MRCTs (sources of variability, heterogeneity, intrinsic or extrinsic factors, differences in treatment effects) • Region specific/site specific interim monitoring • Case study – Multi-regional non-inferiority clinical trial to compare lung surfactant (Could reduce number of case studies and spend more time on case study from Asia.) (18 slides)
14.15-15.00 Case study from Asia (3 cases) (3 Asian speakers – 15 mins each)
15.00-15.15 Break
15.15-16.15 Decision-making in Multi-regional Clinical Trials • DSMB dilemmas in international trials: a case study (Could reduce slides and spend more time on case studies from Asia.) (27 slides) • Considerations for DSMB decision-making: beyond stopping boundaries (19 slides) • Multi-regional clinical trials – How should DMCs look at interim data? (24 slides) • How should DMCs look at multi-national data? (38 slides)
16.15-16.30 Closing Remarks by Professor/Priest/President from DCUMC