



## **CERVIX CANCER RESEARCH NETWORK (CCRN) MINUTES**

**Sunday, December 2, 2012, 3:00pm, Leiden, the Netherlands**

**Attendees:** D.Gaffney(co- Chair), B.Small, M.Bacon, K.Narayan, A.Jhingran, L.Mileshkin, B.Stonebraker, J.Tidy, M.Plante, M.McCormack, J.Martyn, J.Bryce, A.Shevlin, R.Berger, K.Fujiwara, E.Aotani, D.Cantu, A.Meneses, S.Ryu, K.Adema, G.Thomas, T.Fyles.

**Regrets:** H.Kitchener (Chair), E.Pujade-Lauraine, M.Quinn, G.Stuart, P.Eifel, M.Mirza, L.Mell, C.Kunos, B.Votan, S.Sagae, B.Monk, S.Wilailuk, rpc rep.

Trial specific satellite sessions were held. Items discussed included trial-specific QA, funding, insurance, and accrual issues. Trials discussed included:

NCRI INTERLACE – McCormack  
(of note: will add IMRT strat. factor in case of later need.)

NCIC CTG SHAPE (CX 5) – Plante  
(of note: surg. QA covered in protocol; issues re: translations.)

KGOG-Thai TACO – Ryu  
(of note: initial RT QA session Oct. 2012, Vancouver was successful; new issues re: translations.)

ANZGOG OUTBACK – Mileshkin  
(of note: IMRT discussion – Creutzberg's IMRT section from current trial to be considered; issues re: nations' insurances.)

### **ACTIONS:**

\*Mileshkin to obtain IMRT script from Creutzberg.

\*Martyn to ask Harmonization Committee to review member groups' translations policies.

\*Gaffney to investigate Insurance/Indemnity policy for CCRN with Trimble (ie: can for eg: India's OUTBACK insurance be broad enough to cover multiple CCRN studies??) .

**Cervix Cancer Research Network (CCRN) - Quality Assurance (QA) Subcommittee**

**closed session --- Sunday, December 2, 2012, 6:00pm, Leiden, the Netherlands**

**REPORT**

**Present:** D.Gaffney (Chair), B.Small, M.Bacon, K.Narayan, G.Thomas, S.Ryu, L.Mileshkin, M.McCormack, A.Jhingran, B.Stonebraker, J.Martyn, J.Bryce, J.Berek.

**Regrets:** H.Kitchener, M.Quinn, E.Pujade-Lauraine, G.Stuart, P.Eifel, S.Wilailuk, rpc rep., M.Mirza, T.Fyles.

After welcome & introductions, it was stressed that in 2013 the focus for CCRN would be accrual. In 2012 it was felt that the CCRN was successful at getting sites reviewed and activated. Limited efforts will be made in terms of new sites as directed by the CCRN executive committee.

The following sites were discussed:

1) UPDATES on sites:

Tata Memorial (Mumbai,India) – rpc'd, visited, approved --- activating OUTBACK.

Bangalore (India) – visited & rpc'd -- OSLD clarified & approved --- OUTBACK.

Lucknow (India) – visited & rpc'd – OSLD needed (action: Narayan) - OUTBACK.

Trivandrum (India) – rpc'd & visited – report submitted. Awaits approval. (action: Bacon & Kitchener ) OUTBACK.

Lehore (Pakistan) – visited by Narayan & Mirza – action: Narayan re: RT training. OUTBACK

Bangkok (Thailand) – rpc'd & visited, approved – activating TACO.

Siriraj (Thailand) – rpc'd –needs visit (action: KGOG RT, Ryu, Wilailuk & Ops) - TACO.

Promongkutk (Thailand) – rpc pending --- action: Ryu. TACO.

TACO interest from Singapore (withdrawn) , VietNam, and Russia (action: Bacon & Ryu).

Minsk (Belarus) – rpc'd & visited – needs D.M. infrastructure . There was consensus for approval of a small grant. (action: Bacon) - INTERLACE.

Cluj (Romania) – rpc'd & visited – needs D.M. infrastructure. There was consensus for approval of a small grant if requested.(action:Bacon)-INTERLACE.

INTERLACE interest from Ukraine, All India, New Delhi, Capetown, Kenya, (Ghana?). (action: Bacon & McCormack)

No action was taken on the additional sites suggested below due to the required focus on accrual.

Puerto Rico suggested (Kunos). (action: Jhingran).

Czech Republic suggested (Mell). (action: Thomas)

Colombia suggested (Schmeler) – R.Pareja, Instituto de Canerologia, Medellin, Colombia. (actions: Medellin – Jhingran; Bogata: Thomas)

Brazil suggested (Schmeler) – J. Humberto, Barretos Cancer Center, Brazil. (action: Thomas via Souhami).

Jordan (action Fyles & Thomas).

## 2) ROSTERS:

- a. CCRN RT QA site reviewers: Gaffney, Small, McCormack, Narayan, Mirza, Kunos, Mell, Jhingran, Chadha.
- b. Harmonization Ops site reviewers: Bacon, Martyn, Stonebraker, Votan, Aotani, Carty, Negrouk, others considering (for some, availability limited by day jobs)
- c. Recommendation to attempt sending site reviewers geographically local.

## 3) QA :

- a. reviewed policy – always one of two site reviewers non-trial related.
- b. Reviewed Oct. 2012 Recommendations:
  - i. minimum QA – first few patients at each site for each CCRN study .
  - ii. further considerations re: monitoring. **Resolved: responsibility of trial sponsor.**
  - iii. close examination of Follow-up policies and track record at site visits **as per CCRN Checklist.**
- c. Dr. Gaffney will serve as the CCRN rep. on overall GCIG QA initiative.
- d. It was felt to be optimal to have a CCRN rep. on GCIG Membership Committee. **Action: Gaffney will send memo to Membership Committee re: concerns of RT QA criteria for GCIG member groups.**

e. Martyn agreed to serve as CCRN liaison with Harmonization Committee.

4) The CCRN is grateful to the RPC for continued support.

5) FUNDING:

The finances were reviewed. After payment of small grants will be made it was felt appropriate to **request additional funds from the IGCS**. Matching funds will be made available from the GCIG.

Grant submissions will be considered.

Nucletron is a new GCIG Industry Partner and might be considered for added CCRN support in the future.

6) INSURANCES & INDEMNITIES

It was felt necessary to have insurance and indemnities as required by national regulations of countries.

The Harmonization Committee is exploring this issue further.

There being no further business,  
meeting was adjourned (to dinner).

Respectfully submitted:

D.Gaffney

mB