

**GCIG RARE TUMOR Working Group**  
**10 Nov 2015 Jikei University Tokyo**

**MINUTES**

I.Ray-Coquard (Chair), J.Ledermann (co-Chair)

Attendees:

WELCOME, INTRODUCTIONS, CONFLICTS OF INTEREST DISCLOSURES

**RARE TUMOURS Committee**  
Tuesday, Nov.10, 2015, 4:00pm – 6:00pm  
5F Room, Jikei University, Tokyo

**Chair: I.Ray-Coquard**      **Co-Chair: J.Ledermann**  
**Harmonization liaisons: B.Votan/J.Bryce (Ops), BH Nam/J.Paul (Stats)**

**AGENDA**

- Call to Order and Welcome (COI declarations)
- Review/Approval of Minutes/Report of meeting: May 2015
- 1. **Update** on the GCIG consensus review (including pub. and summary of brainstorming event) 10 min
  - Smartphone application for GCIG guidelines
- 2. On-going clinical trials:  
Update on Alienor trial: Ray-Coquard
- 3. New proposals:  
New project on first line CCCov: M McCormack & L Farrelly  
New project for germ cell tumors KGOG: JY Park  
Project carcinosarcoma: M Wilson (PMHC)  
Registry for SCC, next steps: Ray-Coquard/ J Ledermann
- 4. Future Directions: all  
Adjourn

1 **GCIG Rare Tumor report:**

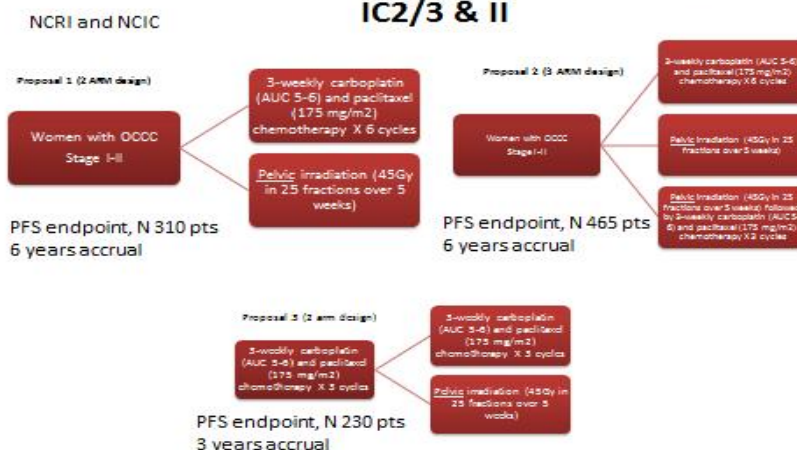
- **Publications :**
  - **Proposal from ESGO : One chapter dedicated to GCIG guidelines for rare tumors in the textbook**
    - **Authors : 20 coordinators + Chair of GCIG in 2013**
    - **Draft circulated next week**
- **IJGC agree for the open access**

- Smartphone application dedicated to GCIG reviews (to discuss with the GCIG webmaster)

## 2. On going clinical trials

- CCC (Ov & Ut)
  - NICC trial (Scottish Group) relapse less than 6 months Mono CT vs. Nintenanib
  - 6/ pts already included
- HGUS
  - EORTC/IRCI 62113-55115 after 1<sup>st</sup> line CT (advanced and relapse) cabozantinib vs. Placebo (cross over at relapse)
  - 6/54 pts included
- SCST
  - Alienor trial (GINECO) relapse after at least one line CT wPacl + bev vs wPacl alone (cross over to bev at relapse)
  - 43/60 pts already included
- All are randomized !
- All well recruited

## 3. Ovarian Clear Cell Trial Proposals- Stage IC2/3 & II

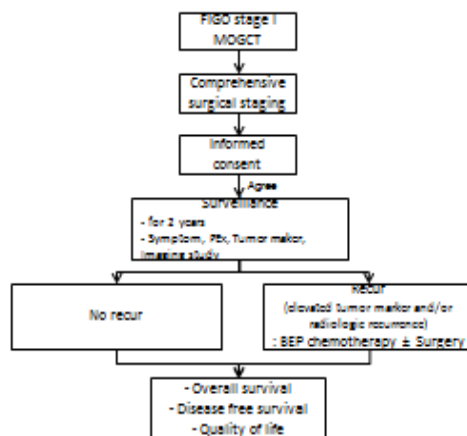


## Recommendations & “To do List”

- Definitively included only IC2/3 & stage II
- Redefine stat plan according to the 5<sup>th</sup> OCCC discussion
- Include endpoints dedicated to PROs
- Collect data ( and tissue) on Stage 1A patients even if they are not entered into the randomization protocol
- Circulate a GICG survey to all national groups looking at interest & favorite model

## 4. Stage I MOGCT & surveillance

- KGOG 3033 study

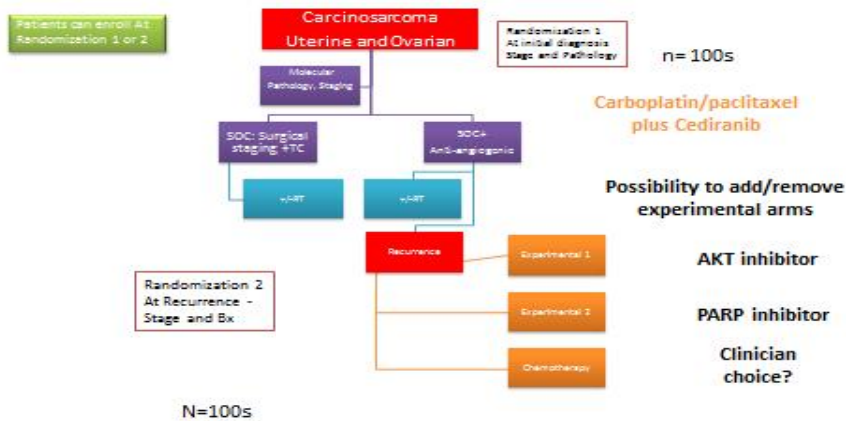


- Inclusion criteria
  - FIGO stage I
  - MOGCT all histologic types
  - Complete staging
  - Age: 0-70 years
- Endpoint
  - 3 years OS
  - 3 year PFS
  - Ovarian function
  - Treatment related complication
- Study duration 4 years
- N = 100 pts

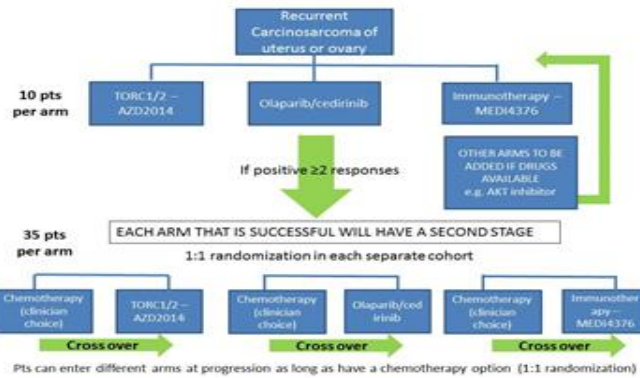
## Recommendations & “To do List”

- Revision of the protocol
  - the extent of surgical staging
  - Schedule of visit/markers/CT-scan for surveillance
  - Statistical plan needed if assumptions about expected 3 or 5 year survival, or recurrence free survival are set
  - Data registry will allow data on long term follow up to be collected
  - Include dedicated endpoints to PROs
- Get consent for patients not wishing to go on surveillance so that outcome data (especially tox) can be collected
- Next version before Chicago & proposal to national groups to participate

## 5. Ov & UT carcinosarcoma (PMHC project)



A randomized phase II trial **MULTI-arm Study** comparing targeted therapy with chemotherapy at recurrence in **Carcinosarcoma of the ovary and uterus (MUSIC)**.



## Recommendations & "To do List"

- Suggestion of combining ovary and uterus CS is an issue
  - Probably focus on Uterus
  - Endpoint of first section treatment considered optimistic. Increase in PFS from 8 to 13 months. Suggested that stats be reconsidered.
  - Defined guidelines for histologic diagnosis
- Recurrent study in 2 parts – run in 10 patients then randomization to a series of novel agents- umbrella design.
  - RR primary endpoint of both run in and randomization study - suggested that SD, or Prog-free at 3 or 6 months might be preferable.
  - First stage of recurrent disease probably more easily done by 1 group, the 2<sup>nd</sup> phase of the recurrent disease trials could be distributed although numbers per treatment group are small-35.
- Include endpoints dedicated to PROs
- Next version is waited

## 6. GCIG SCCOHT Project

- **Summary 2014/2015:**

- **Steering Committee: Clinicians, pathologist, scientist, study coordinator (operations), statistician**
- **International Registry (prospective & retrospective)**
- **Biorepository for TR**
- **Registration of outcome data for efficacy on all CT regimens used (1<sup>st</sup> line therapy & relapse)**
  - Helping us to upgrade the quality of GCIG guidelines
  - Potential trials of novel agents for relapsed patients

The image displays two screenshots of the Case Report Form (CRF) for Small Cell Carcinoma of the Ovary (SCCO). The left screenshot shows the 'PATIENT DEMOGRAPHIC DETAILS' section, including fields for Patient ID, Center Initials, and Record number, followed by sections for 'I. DEMOGRAPHIC DETAILS' and 'II. PRESENTATION'. The right screenshot shows the 'FIRST LINE THERAPY' section, detailing chemotherapy regimens, hormone therapy, and other treatments with various checkboxes and dropdown menus for selection.

### Recommendations & “To do List”

- Data form to be circulated.
- Enquiries re cost of accessing :
  - Redcap or Cartwheel database (Clare Scott).
  - Mario Negri database ( Heavy base?) Free of charge? ( Nicoletta Colombo to investigate).
  - Mega database group (Ros Glasspool)
- Many countries have emerging RT registries. The step from registry to clinical data collection needs to be made by most.
- GCIG survey (Ray-Coquard) will circulated to national group :
  - National organization yes/no
  - National barrier to send data
  - Estimated nb of patients
  - On going collection of tumors
- 1<sup>st</sup> initiative to collect retrospective information from national groups via Excel files to have quick information available

Anticipated to organize TC and mail exchange every 2 months to follow the process of the 3 projects

**Adjourn**