GCIG **RARE TUMOR Working Group**

Thursday 30th June 14:00 a.m. – 16:00 am

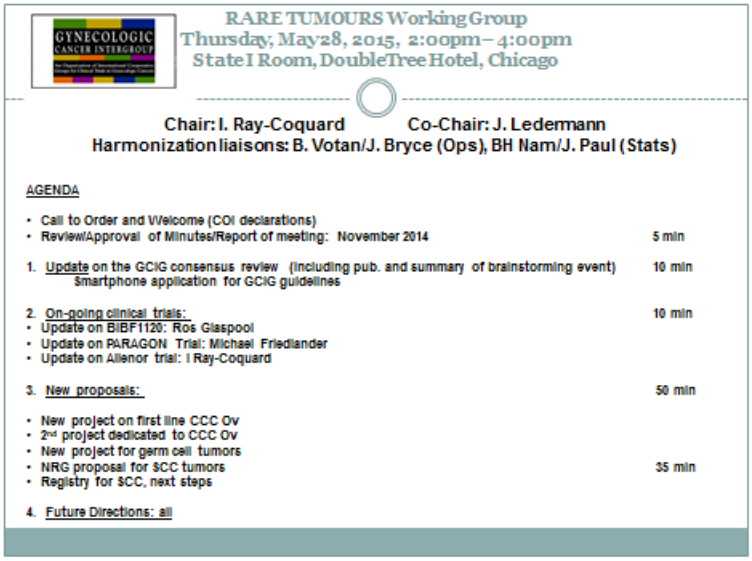
Chicago

MINUTES

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

Attendees:

WELCOME, INTRODUCTIONS, CONFLICTS OF INTEREST DISCLOSURES


RARE TUMOURS Working Group
Thursday, May28, 2015, 2:00pm–4:00pm
State I Room, DoubleTree Hotel, Chicago

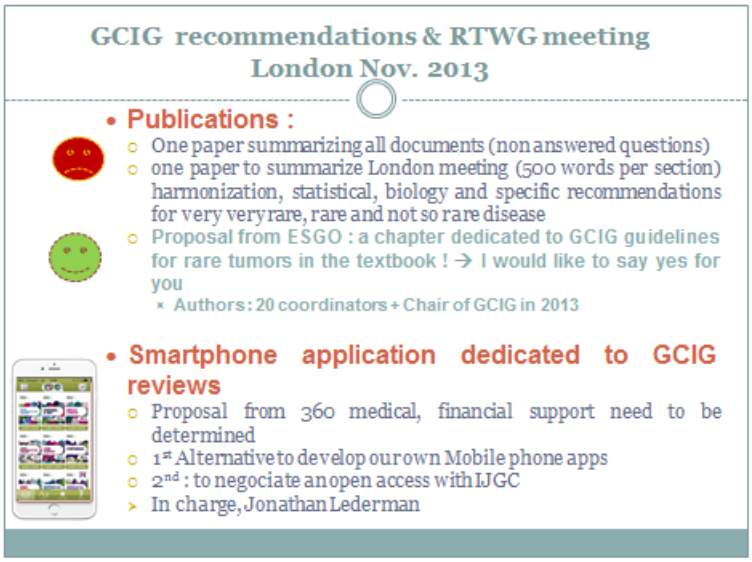
Chair: I. Ray-Coquard Co-Chair: J. Ledermann
Harmonization liaisons: B. Votan/J. Bryce (Ops), BH Nam/J. Paul (Stats)

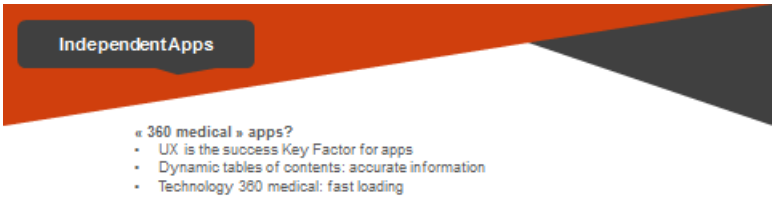
AGENDA

- Call to Order and Welcome (COI declarations)
- Review/Approval of Minutes/Report of meeting: November 2014 — 5 min

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: — 10 min
   - Update on BIBF1120: Ros Glaspool
   - Update on PARAGON Trial: Michael Friedlander
   - Update on Allenor trial: I Ray-Coquard
3. New proposals: — 50 min
   - New project on first line CCC Ov
   - 2nd project dedicated to CCC Ov
   - New project for germ cell tumors
   - NRG proposal for SCC tumors — 35 min
   - Registry for SCC, next steps
4. Future Directions: all

1 **GCIG Rare Tumor report:**





Agreement from Ex-Co is waiting for smartphone application project and financial support

2. Clinical trial on – going:

NiCCC
Nintedanib in Clear Cell Carcinoma

A Randomised Phase II Study of BIBF 1120 versus Chemotherapy in Recurrent Clear Cell Carcinoma of the Ovary or Endometrium

SGCTG/NCRI/NSGO

NiCCC Trial Design

Paragon

A Phase II study of aromatase inhibitors in women with potentially hormone responsive recurrent/metastatic gynaecological neoplasms

Tumour Subgroup Accrual

Tumour Subgroup	Accrual
*Ovarian - Asymptomatic patients with rising CA125 markers	54
Ovarian - Low Grade / Borderline Tumours	23
*Ovarian - Platinum Resistant / Refractory	53
*Endometrial Carcinoma	83
Endometrial Stromal Sarcomas	14
Miscellaneous Sarcomas	27
Granulosa Cell & Sex Cord Stromal Tumours	32

*Tumour subgroups have met accrual target and are now closed to recruitment

Trial Status

Country/Group	Sites	Accrual
ANZGOG	23	205
United Kingdom	23	80
Belgium	1	1
TOTAL	**47**	***286**

*Accrual target is 350 patients

Transparagon trial is on going to be organized

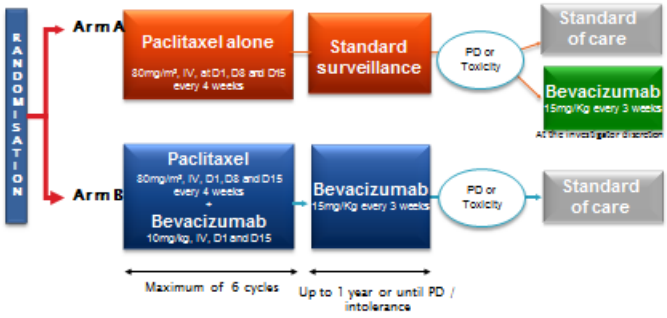
ALIENOR

ENGOT- OV7

Avastin and weekly pac**LI**taxel use in s**E**x cord-stromal ovaria**N** tum**OR**s

A randomized, open label, phase II trial of bevacizumab plus weekly paclitaxel followed by maintenance with bevacizumab monotherapy versus weekly paclitaxel followed by observation in patients with relapsed ovarian sex-cord stromal tumors

ALIENOR DESIGN : 60 patients

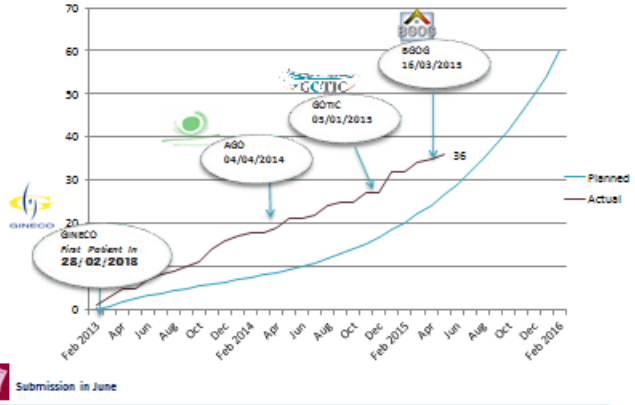


Population :
Patients with an histologically confirmed diagnosis of **ovarian sex-cord stromal tumor** in relapse after a platinum-based chemotherapy.

Primary objective :
Clinical benefit rate
(non-progression rate after 6 months of treatment)

Stratification
Anterior chemotherapy lines :
1 or 2 vs 3 and more
Platinum Free Interval Interval (PFI)
<12 months vs ≥12 months

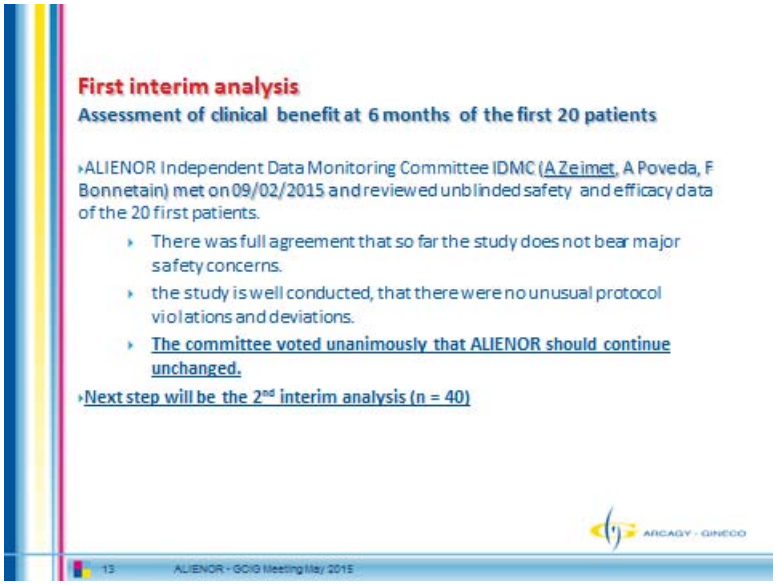
ALIENOR Status



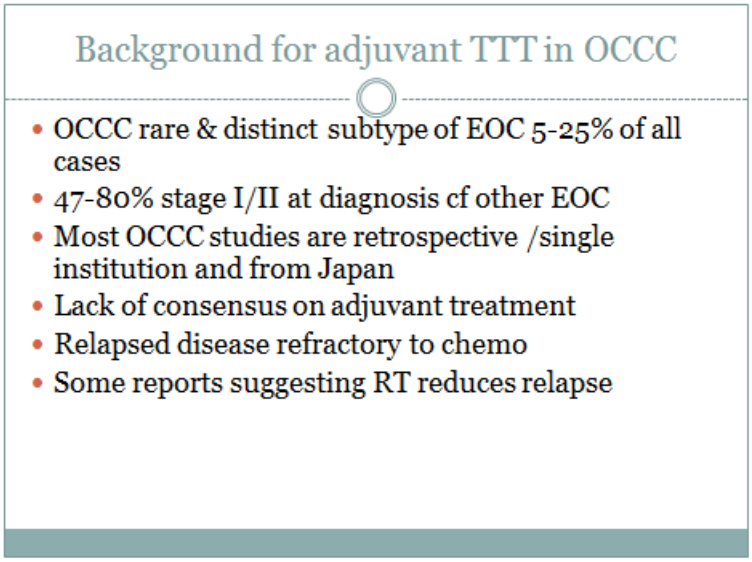
Submission in June

- Enrollment period : *36 months*
- Treatment + maintenance : *18 months*
- Follow-up : *36 months*

First Patient In : *February 2013*
Last Patient Out of Maintenance : *August 2017*
Last Patient Out : *August 2020*



3. New projects
   3.1. Clear cell carcinoma (ovarian localization)



Early stage CCC ovarian carcinoma

- 2 proposals:
  - From NRCN (Mary McCormack)
    - Stage IC to II
    - Pelvic radiotherapy vs 6 cycles CP
    - Phase III trial,
    - PFS HR 0,65; n≈ 500/600pts
  - From Canadian group (reported by Iain McNeish)
    - Stage IC2 to II
    - 3 cycles CP then ® 3 cycles CP vs pelvic RT
    - Randomized phase II
    - N= 106 pts, OS HR 0,6

Early stage CCC ovarian carcinoma

- Recommandations:
  - Only one Clinical trial
  - No stage IA or IB (excellent prognosis)
  - Central review of the histology
  - Optimal control arm not clearly defined
    - JGOG currently evaluated obs vs CT
  - Late toxicity major issue for RT
  - Surgery need to be clearly defined
  - All questions will be circulated
  - Final version for Nov 2015

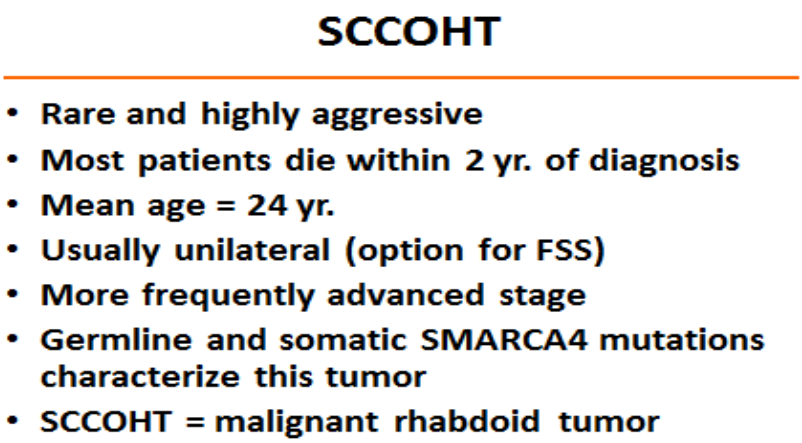
3.1. GCT proposals

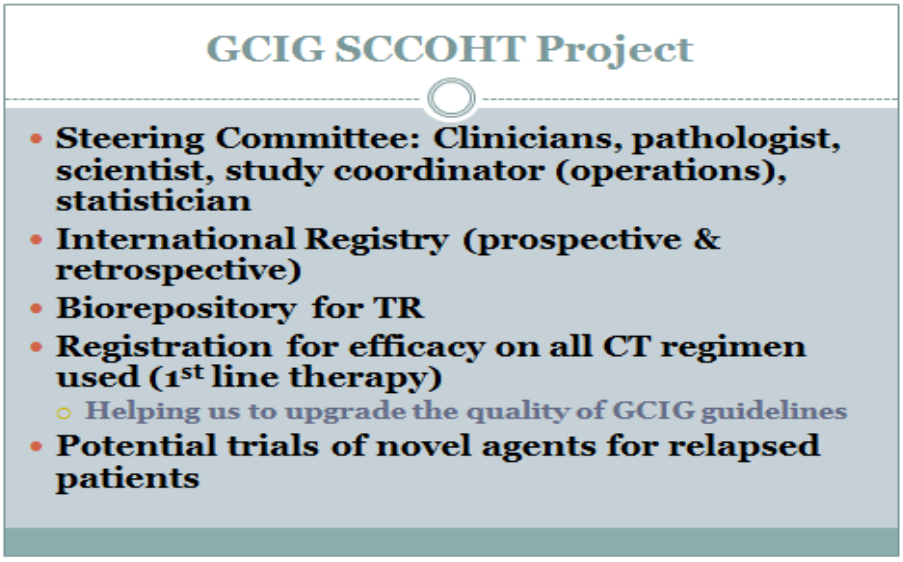
Proposed International Malignant GCT Trial

- **From the MAGIC consortium (A. Lindsay Frazier):**
- **GCT (testis & ovarian) child & adult**
  - **Low risk (FIGO Stage IA/B): observation only after surgery**
  - **Intermediate Risk (FIGO Stage II, III): RCT of JEB vs. BEP**
  - **Poor Risk (FIGO Stage IV): RCT of BEP vs. T-BEP vs. Accelerated BEP or TIP.**
  - **Need for a GCIG participation, however, not a GCIG trial until today**

4. Small Cell Carcinoma registry project

Previously on 2014:





So, today next steps will be:


SCCOHT, next steps
1st registry including retrospective & prospective data on treatments & survival + availability of tumors +/- blood:
Coordinator & Steering committee will be defined
Call for application (now)
Objectives: description of the clinical management & prognosis, identification of patients & tumor samples
To be included in the mega databasis project?
2nd point: clinical trial dedicated to SCCOHT
Drugs : BRM-ATPase inhibitors , HDAC inh,
Major Questions & Design

Adjourn