GCIG Rare Tumor Working Group Report

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Ted Trimble

NCRN

CANCER RESEARCH UK

NATIONAL CANCER INSTITUTE

EORTC
European Organisation for Research and Treatment of Cancer

IRCI - Aims

- To facilitate the development of international clinical trials of treatments for rare cancers
- Encourage innovative methodologies to maximise potential for answering research questions
- To identify and overcome barriers to international trials so that agreed IRCI trials can run smoothly

IRCI
International Rare Cancers Initiative

IRCI – partner organisations

Core activities of the Initiative

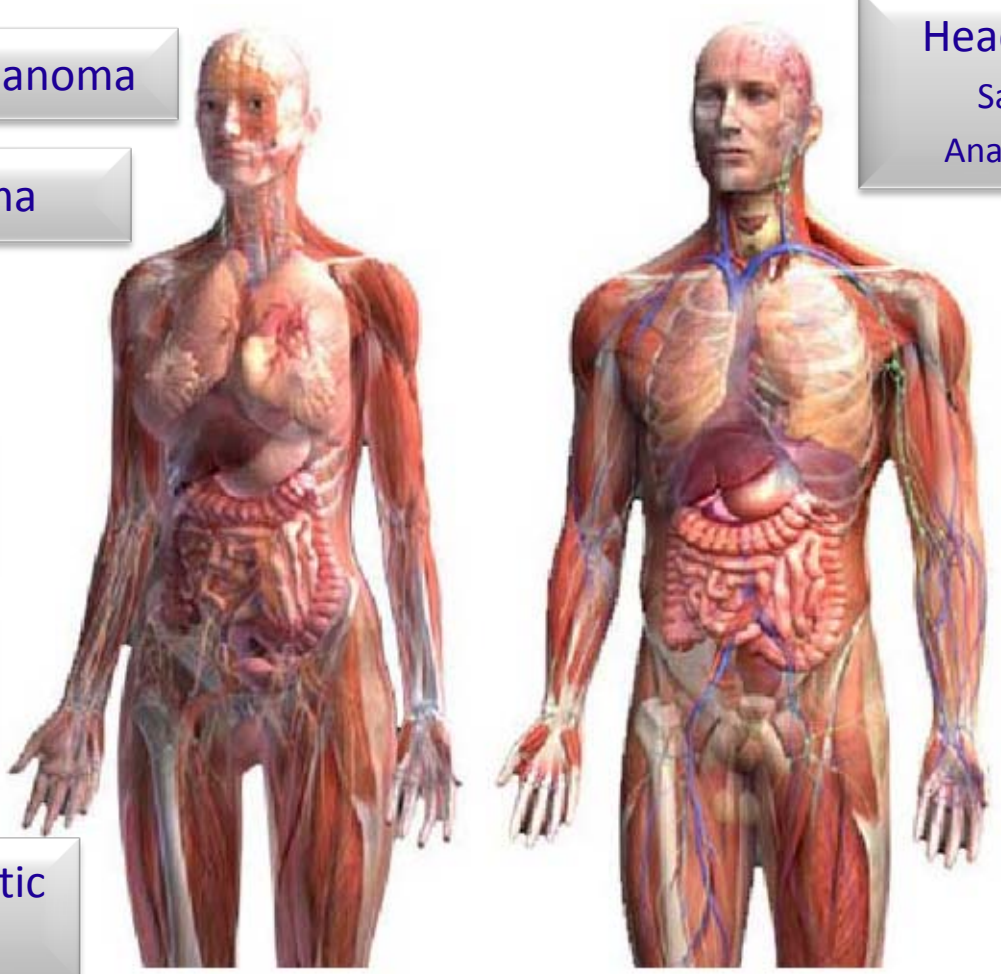
Ocular melanoma

Thymoma

Gynaecological sarcoma

Small bowel adenocarcinoma

Relapsed/metastatic anal cancer



Head and neck cancer

Salivary gland cancer

Anaplastic thyroid cancer

Fibrolamellar hepatocellular carcinoma

Penile cancer

IRCI

International Rare Cancers Initiative

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

SGCTG/NCRI/NSGO

GCIG Chicago 2012

Trial Design

90 pts with progressive or relapsed CCC of ovary within 6 months of previous platinum.

Plus up to 30 women with endometrial CCC

RANDOMISE

Chemotherapy

Ovary:

- PLDH (40mg/m^2 day 1q28)
- Weekly Paclitaxel (80mg/m^2 day 1, 8, 15 q28)
- Weekly Topotecan iv (4mg/m^2 day 1, 8, 15 q28)

Endometrium:

- Carboplatin (AUC 5) /Paclitaxel 175 mg/m^2 q21
- Doxorubicin 60mg/m^2 q21

BIBF 1120 200mg bd until progression

Primary Endpoint: PFS

Secondary Endpoints: OS, Toxicity, RR, QoL, Q-Twist

Trial Status

- Joint project with NSGO with collaboration with GINECO and EORTC
- Trial supported by Boehringer Ingelheim and by Cancer Research UK
- Protocol now in development

scottish gynaecological cancer trials group

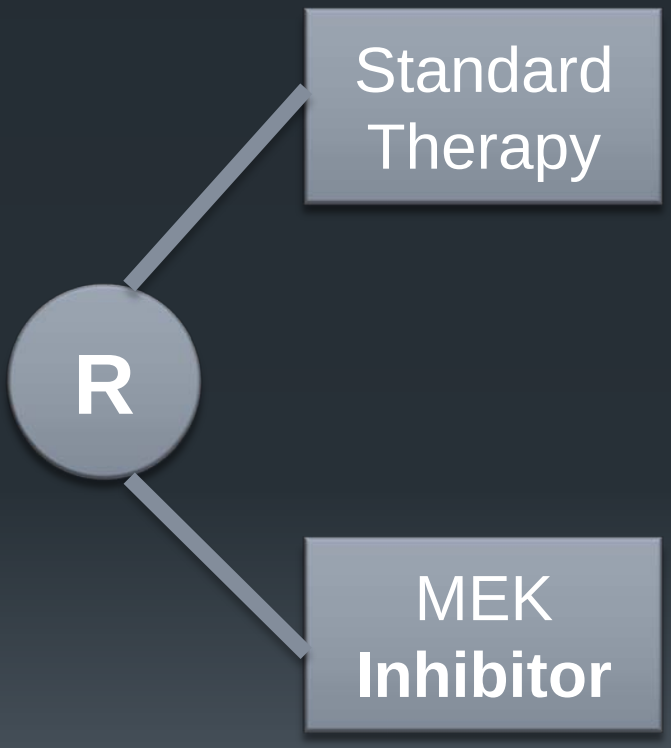
NCRI National Cancer Research Institute

NSGO

RTM1103

- Phase II trial of AMG 386 for recurrent sex cord-stromal tumors of the ovary (Chan)

RTM1104



Sample Size = 230 pts

Primary Endpoint: PFS

Secondary Endpoints: Response, OS

RTM1205

- Proposed international study for malignant germ cell tumors:
  - COG
  - GOG
  - UK Pediatric Group
- Low-risk cohort: Surveillance
- Intermediate-risk cohort: BEP variation
- High-risk cohort: More aggressive therapy

CART-WHEEL
Center for Analysis of Rare Tumors

BIOGRID AUSTRALIA
Health through information

CART-WHEEL.org for rare gynaecological tumor research

Clare Scott

Medical Oncologist, RMH
Laboratory Head, WEHI
MBBS PhD FRACP

FIAT LUX
Walter+Eliza Hall
Institute of Medical Research

MELBOURNE HEALTH

How does CART-WHEEL work?

MELBOURNE HEALTH

HREC approved (Melb Health 2007)

Website/database design started in 2008

Provides information to consumer about research

Patients or their representative can:

- register
- enter their data into streamlined questionnaire
- down-load, sign and post consent form

CART-WHEEL
Center for Analysis of Rare Tumors

How does CART-WHEEL work?

Data obtained focuses on:

- accurate histologic diagnosis
- location of histology report
- location of biopsy / surgical block

Collection of treatment, toxicity, follow-up data

General morbidity, family history of cancer

Molecular testing of patient/family or tumour

CART-WHEEL
Center for Analysis of Rare Tumors

CART-WHEEL

Center for Analysis of Rare Tumors

Click here for a summary of the whole page, or place the cursor over any of the underlined words for a description

3. What type of tumor do you have?

If you have a Biopsy/Histology report from your doctor please type in the diagnosis as shown on the report.
If you have had any other tumors apart from this tumor you can specify this in Question 15.

Start typing the name of the tumor into the text field. You can choose one of the suggested types which will appear or enter another name.

(Ovary) Small cell carcinoma

3a. When was your tumor first diagnosed?

Please select the date corresponding to the date on which your tumor was diagnosed. If you are not sure, please select a date around the time that you recall your tumor was first diagnosed and click on the box saying 'Estimated Date'.

Day | Month | Year ☐Estimated Date

< PREVIOUS | SAVE | SAVE AND NEXT >

Patient chooses level of consent

I give my permission for my data to be stored in the Rare Tumour Database and **to be used in a re-identifiable** (coded) way

☐ YES ☐ NO

I give permission for BioGrid Australia to **contact me for updates** of my personal information

☐ YES ☐ NO

I give my permission for BioGrid Australia to **contact my doctor to obtain my histologic report(s) and medical details** to confirm tumour type

☐ YES ☐ NO

I give my permission for BioGrid Australia to **contact me regarding participation in an ethically-approved research project**

☐ YES ☐ NO

CART-WHEEL
Center for Analysis of Rare Tumors

Advantages for Consumers

Learn about research

Contribute their data for research

Signal their wish to be involved in research

Contacted for a clinical trial or research study

Print off their **pdf summary** anytime

Help to **drive the direction** of research into areas which currently are “too hard”

CART-WHEEL
Center for Analysis of Rare Tumors

Advantages for Researchers

Access to patient data and location of tissue

- Includes field for Biobanking
- FFPE blocks will become more and more useful…

Patient-specific consent, data-entry are streamlined

Need to have an HREC-approved study: can include in that an additional consent form to be sent to pt for access to tissue or request waiver to access tissue

CART-WHEEL
Center for Analysis of Rare Tumors

GYNET- European NETwork for rare Gyneacologic cancers

- **General objective :**
  - GYNET project aims at setting up a EU network of leading groups and institutions in the management of Rare Gynecological tumors based on a web-based platform, for contributing to the improvement of RGT treatment.

- **Total grant requested : 975 761€**

- **Calendar (estimated)**
  - Results : Summer 2012
  - Negociation : Fall 2012 : **During negociation phase, EC might request modifications in tasks, partnership, budget etc. The final contract is only signed, and binding, after the negociation phase**
  - Project execution (if funded) : January 2013 - December 2015

ALIENOR

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

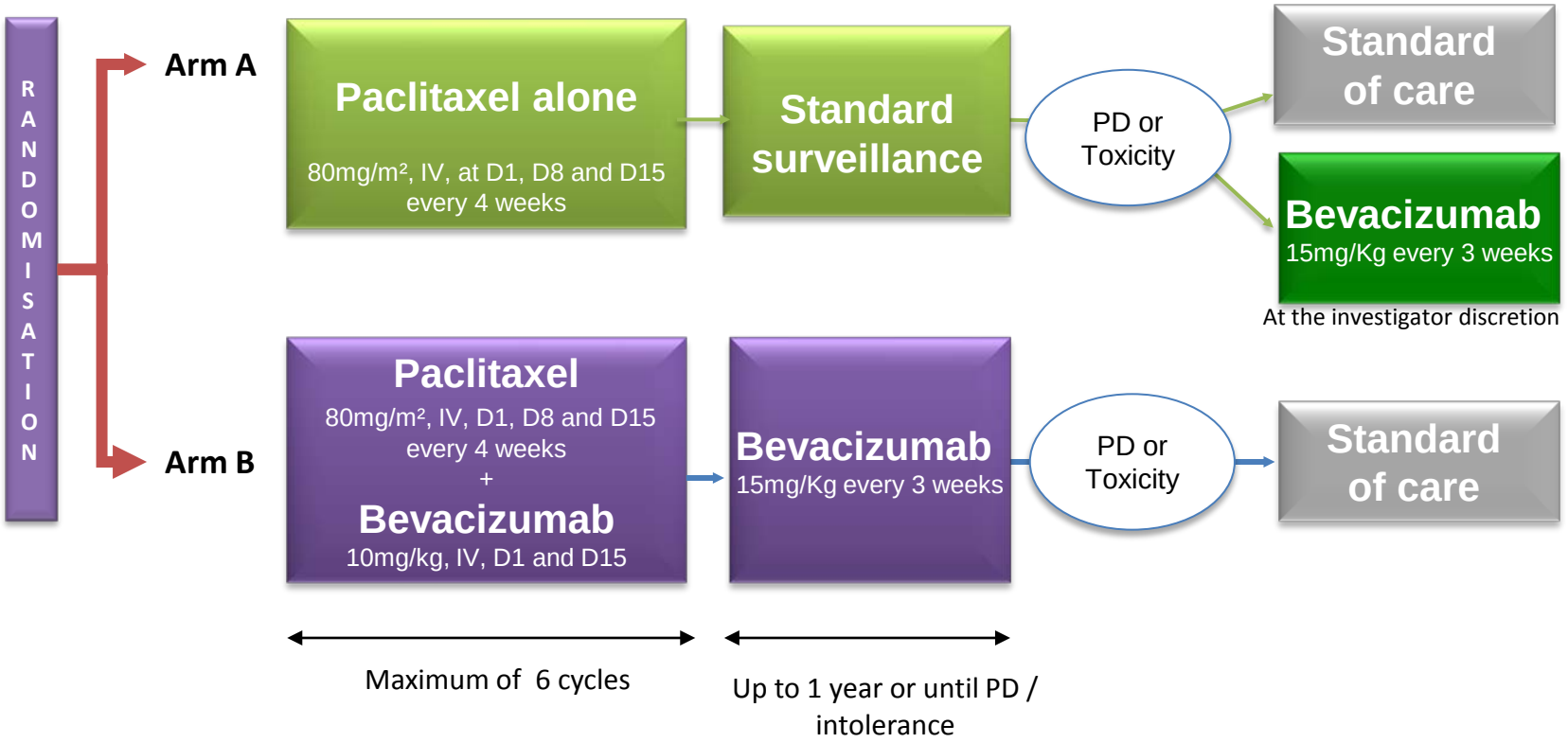
An European, randomized, open label, phase II trial of bevacizumab plus weekly paclitaxel followed by maintenance with bevacizumab monotherapy versus weekly paclitaxel followed by observation in patients with relapsed ovarian sex-cord stromal tumors

Participating Groups

GINECO, MITO

ANZGOG (tbc) , EORTC (tbc) , AGO (tbc) , GEICO (tbc) , JGCO (tbd)

ALIENOR DESIGN : 60 patients

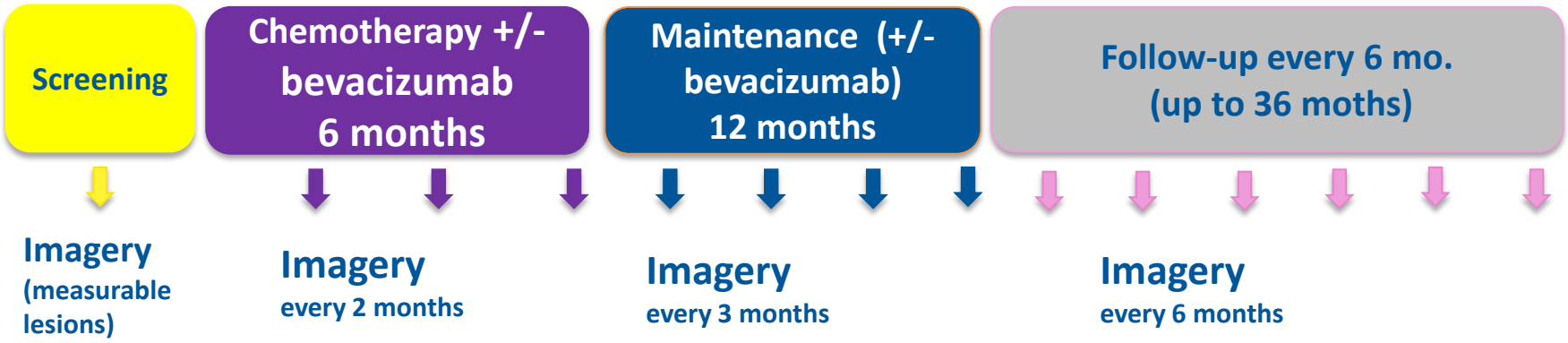


Enrollment period : *36 months*
Treatment + maintenance : *18 months*
Follow-up : *36 months*

First Patient : *October 2012*
Last Patient Out of Maintenance : *April 2017*
Last Patient Out : *April 2020*

PRIMARY ENDPOINT

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



❖Mandatory : Central (national level) review of the Progression

Update on GCIG Rare Tumor Initiative

- N Reed, 1999- 2009:
  - Ovarian Carcinosarcoma (G Rustin & N Reed);
  - Low Malignant Potential Tumours (J Pfisterer);
  - Sex Cord Stromal Tumor (N Reed & ?);
  - Uterin Carcinosarcoma (N Reed);
  - Low Grade Endometrial Stromal Sarcoma (KD Swenerton and CB Gilks);
  - Pseudomyxoma Peritonei (P Harper).

Update on GCIG Rare Tumor Initiative

- 2012 –
  - Update previous versions and publication for the GCIG group
  - New dedicated « guidelines » or « guidances » for :
    - Germ cell tumors
    - Small cell carcinoma ov & cervix
    - Vulvar & vagina carcinoma
    - Vulvar & vagina melanoma
    - Uterus sarcoma
    - Mucinous carcinoma
    - Clear cell carcinoma
    - Low grade serous carcinoma …..