

## GCIG Rare Tumors Working Group BRAINSTORMING DAY

# International Rare Tumor Initiative (IRCI)



Thomas Gross, MD, PhD  
Center for Global Health  
National Cancer Institute  
Bethesda, MD 20892

Email: [Thomas.gross@nih.gov](mailto:Thomas.gross@nih.gov)

# International Rare Tumor Initiative (IRCI) Background

- No fixed incidence exist to define “rare” cancers
  - IRCI guide  $<2/100,000$
- Rare cancers account for 20-25% of all cancers
  - 5 yr. survival “rare” cancers is 45% vs. 65% for “common” cancers
- There is little known about pathological and molecular patterns
- Therapeutic options are poorly documented and remain essentially empiric



# International Rare Tumor Initiative (IRCI) Rationale

1. Some cancers are so rare that **accrual from individual networks would not provide enough patients to perform meaningful clinical trials**. The only way to make progress in these cancers is to merge the accrual base of several organizations. International accrual will shorten trials:
  - decrease trial duration and trial failure
  - allow more rapid development of treatments.
2. **Rare cancer trials are resource-intensive**, but the burden can be spread among multiple partners.
3. Exploration of rare cancers **will provide insight into mechanisms applicable to other cancer or diseases**.
4. The **linkages and joint processes developed in this initiative will facilitate international collaboration in more common cancers** and in biologically-defined subsets of those cancers.

# International Rare Tumor Initiative (IRCI)

- IRCI was established in 2011
- Members
  - Cancer Research Network (NCRN) and Cancer Research UK (CRUK)
  - National Cancer Institute (NCI) in the US
  - European Organisation for Research and Treatment of Cancer (EORTC)
  - Institut National du Cancer (INCa) in France (2013)
- Membership
  - National/international cancer clinical trials group
  - An associated funding body
  - Commitment to materially support core operations of IRCI
  - Approval by majority of existing IRCI members
  - Transact a Memorandum of Understanding (MOU) with IRCI



# International Rare Tumor Initiative (IRCI) Functions

1. Bring together international experts in rare cancers and member organizations that have the capacity to perform clinical trials across national boundaries.
2. Provide a forum for member organizations to prioritize global rare cancer strategies.
3. **Coordinate discussion of clinical trials in cancers that otherwise lack international organizing infrastructure.**
4. **Facilitate review of concepts and protocols by member organizations.**
5. Work to lower barriers to performance of international clinical trials in cancer.
6. Provides a common voice for academic clinicians to approach industry for worldwide collaboration in rare cancer clinical trials.



## International Rare Tumor Initiative (IRCI) Disease Committees

### **Head and Neck cancer (Salivary Gland Cancer)**

Leads: Dr Kevin Harrington (UK), Dr Alan Ho (US), Dr Lisa Licitra (EORTC)

### **Anaplastic thyroid cancer**

Leads: Dr Keith Bible (US), Dr Laura Moss (UK), Professor Patrick Schöffski (EORTC)

### **Small bowel adenocarcinoma**

Leads: Dr Rob McWilliams (US), Dr Arnaud Roth (EORTC), Dr Richard Wilson (UK)

### **Gynaecological sarcoma**

Leads: Professor Jean-Yves Blay (EORTC), Dr Helen Hatcher (UK) Dr Martee Hensley (US)

### **Fibrolamellar hepatocellular carcinoma**

Leads: Dr Michel Ducreux (EORTC), Dr Marcio Malogolowkin (US), Dr Tim Meyer (UK)

### **Penile cancer**

Leads: Dr Steve Nicholson (UK), Dr Curtis Pettaway (US), Dr Christine Theodore (EORTC)

### **Thymoma**

Leads: Professor Frank Detterbeck (US), Professor Mike Lind (UK), Dr Sanjay Popat (EORTC)

### **Ocular melanoma**

Leads: Dr Richard Carvajal (US), Dr Ernie Marshall (UK), Professor Poulam Patel (EORTC)

### **Relapsed/metastatic anal cancer**

Leads: Professor Dirk Arnold (EORTC), Dr Al Benson (US), Dr Rob Glynn-Jones (UK)

## International Rare Tumor Initiative (IRCI) Clinical Trials Characteristics

- **Lack of existing trials**
  - IRCI exists to develop new trials where there is no (or minimal) existing trial data and no existing trial.
  - **not intended to compete with (or boost) existing trials.**
- **Potential for an interventional trial**
  - **Priority is given to randomized trials**
  - Audit, registry or non-trial tissue collection trials are not a priority
- **Enthusiastic champions**
  - commitment from investigators to propose trial ideas and act as Principal Investigators is essential.

# International Rare Tumor Initiative (IRCI) Trial Development

1. The IRCI serves as a central forum for development of new international clinical trials in rare cancers. **The IRCI itself does not approve trials on behalf of its member organizations.**
2. A clinical investigator developing a new concept submits the concept to his/her respective member organization through normal review channels. That organization is the “trial lead” organization and may approve, disapprove or request modification of the concept, per their standard procedures.
3. Once the lead organization has endorsed a concept, the concept will be forwarded to other partner organizations that have expressed interest. The partner organizations will follow their own review procedures, but for the sake of efficiency, may opt to accept the review of the lead organization.
4. **A clinical trial can be badged as an IRCI initiative as long as two member organizations agree to conduct the trial.**

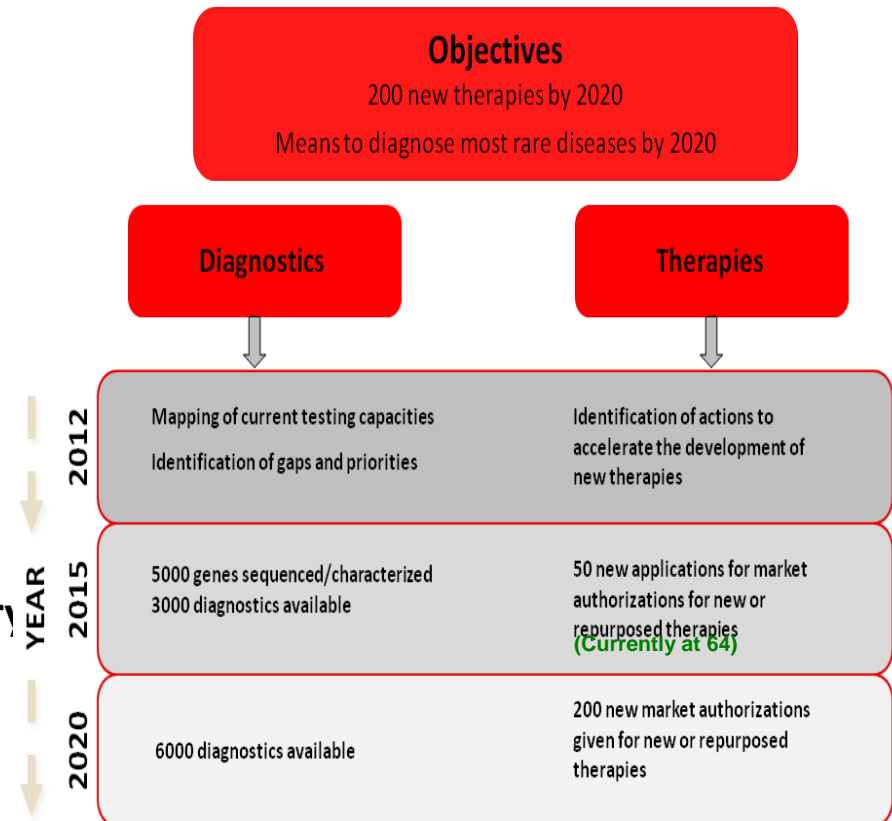




Type of cancer	Trial title	Lead
Salivary gland	A randomised phase II study to evaluate the efficacy and safety of Chemotherapy (CT) vs androgen deprivation therapy (ADT) in patients with recurrent and/or metastatic, androgen receptor (AR) expressing, salivary gland cancer (SGCs)	EORTC, BE
Uveal melanoma	A randomized Two-ARm Ph II study of Trametinib Alone and in Combination with GSK2141795 in Patients with Advanced Uveal Melanoma	MSKCC, USA
Gynecological sarcoma: uLMS	A Phase III Randomized Trial of Gemcitabine plus Docetaxel followed by Doxorubicin v. observation for uterus-limited, High Grade Uterine Leiomyosarcoma	GOG, USA
Gynecological sarcoma: HGUS	A randomized phase II study evaluating the role of maintenance therapy with pazopanib in High Grade Uterine Sarcoma (HGUS) after stabilization or response to chemotherapy following surgery or in metastatic first line treatment	EORTC, BE
Thymoma	Randomized study of resected stage III invasive Thymoma or stage II-III Thymic carcinoma with or without postoperative radiation therapy	Alliance, USA
Penile cancer	Randomized study of resected stage III invasive Thymoma or stage II-III Thymic carcinoma with or without postoperative radiation therapy	Alliance, USA
Anal cancer Penile cancer	InPACT – International Penile Advanced Cancer Trial	NCRI, UK
Anal cancer	InterAAct, A Phase II International Multicentre Randomized Advanced Anal Cancer Trial Comparing Cisplatin plus 5FU vs. Carboplatin plus Weekly Paclitaxel in Patients with Relapsed or Metastatic Disease	NCRI, UK

# International Rare Disease Research Consortium (IRDiRC)

- Challenges are being addressed through collaborative actions to reach these **2020 goals** such as:
- establishing and providing access to harmonized data and samples,
  - performing the molecular and clinical characterization
  - **boosting translational, preclinical and clinical research**
  - **streamlining ethical and regulatory procedures.**





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