

## Cervix Cancer Research Network

**Chair: Mary McCormack** 

Steering Committee: Marie Plante, David Gaffney, Sang Young Ryu, Bill Small, Carien Creutzberg, D. Thinh, Anuja Jhingran, Linus Chuang ,Linda Mileshkin, Al Covens (IGCS), Jonathan Berek (FIGO) and Monica Bacon

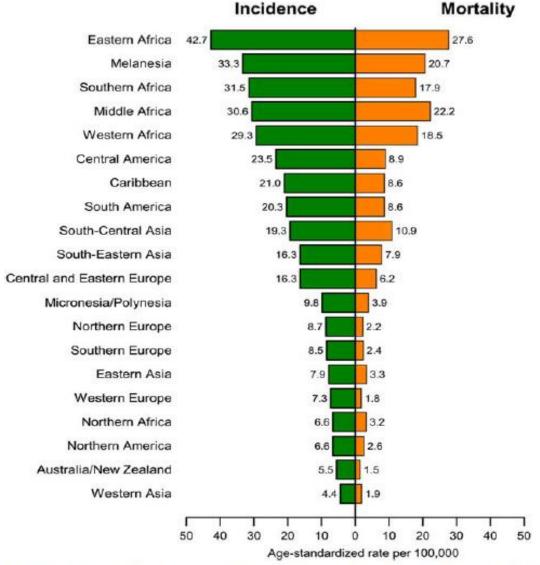
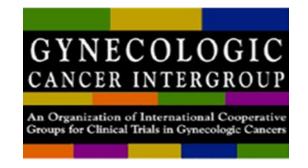


FIGURE 11. Cervical Cancer Incidence and Mortality Rates by World Area.

Global Cancer Statistics, 2012. CA Cancer J Clin;65-87-108, 2015



- 4<sup>th</sup> most common cancer women
- Over 500,000 new cases/260,000 deaths per year
- Mortality varies2-27/100,000
- Cancer burden likely to rise



#### Health, equity, and women's cancers 1

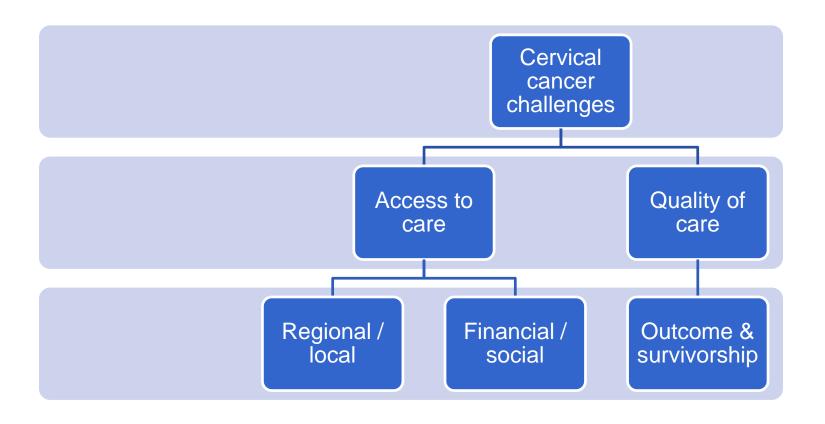


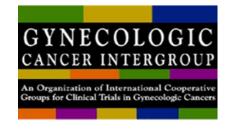
## The global burden of women's cancers: a grand challenge in global health

Ophira Ginsburg, Freddie Bray, Michel P Coleman, Verna Vanderpuye, Alexandru Eniu, S Rani Kotha, Malabika Sarker, Tran Thanh Huong, Claudia Allemani, Allison Dvaladze, Julie Gralow, Karen Yeates, Carolyn Taylor, Nandini Oomman, Suneeta Krishnan, Richard Sullivan, Dominista Kombe, Magaly M Blas, Groesbeck Parham, Natasha Kassami, Lesong Conteh

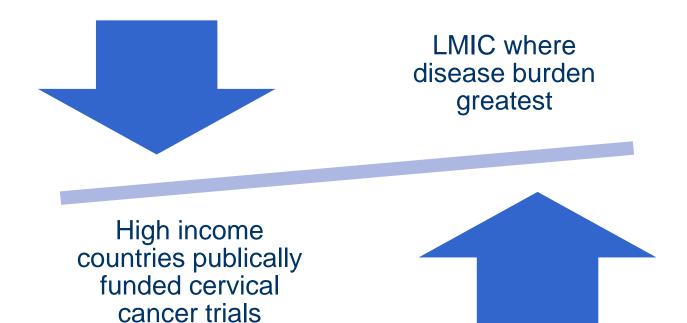
Lancet 2017,389

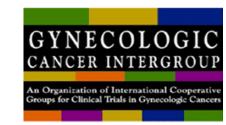






#### **Cervical Cancer**





## **CCRN** background

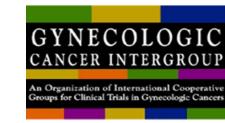
GCIG established 1993

Currently comprises 29 cooperative groups

Main mission is to promote academic trials in Gyn cancer

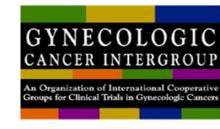
**CCRN** 

Interested sites in areas where national cooperative groups not yet established



## What is CCRN?

- A Network of sites with expertise in the management of cervical cancer
- Established in 2011 by Prof Henry Kitchener & managed by GCIG
- These sites are generally in LMIC
- Common goal to promote research and good clinical practice in the treatment of women with cervical cancer
- Recognised that participation in research raises the standards for all patients.
- Inclusion of patients from diverse ethical and cultural backgrounds in clinical trials is essential to validate potentially practice changing approaches.



#### **Current CCRN studies**

EARLY STAGE DISEASE

SHAPE (NCIC)

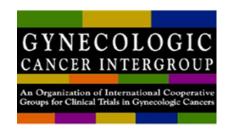
SENTICOL III(GINECO)

LOCALLY ADVANCED

INTERLACE (NCRI)

TACO (KGOG)

Hypofrac (G-GOC)

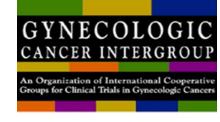


# CCRN standard operating procedure

Expression of interest

Prequalifying & Capability questionnaire

Site visit for verification



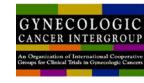
## Prequalifying questionnaire

- Site information-contacts/ number of cancers/Gyn ca/Cervix
- Site resources-pathology/radiology/ IT/ indemnity insurance
- Clinical trials ops-CTU/Personnel /tumour boards/ previous trials experience/details of ethics and regulatory approval processes
- Radiation therapy –facilities/documentation/dosimetry audit/treatment verification/patient pathway

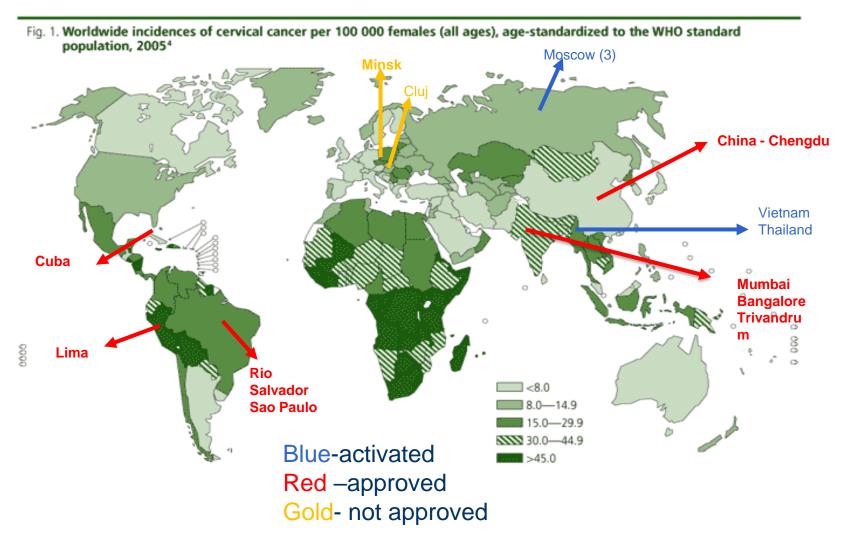


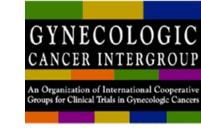
## Capability questionnaire

- 1. Are your clinical trial subjects entitled to medical management without cost as long as required; and entitled to financial compensation for clinical trial related injury or death?
- 2. Do you have (national) definitions of what constitutes 'clinical trial related injury or death'?
- 3. Do you follow ICH Good Clinical Practice [GCP] Guidelines?
- 4. As well as protocol-mandated reporting through the data reporting mechanism, is there a national regulatory procedure for reporting serious adverse events .



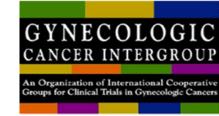
#### **Current CCRN sites**





## Meeting objectives

- Establish new partnerships to further care of women with cervical cancer
- Facilitate the exchange of ideas in developing new trials
- Highlight ongoing CCRN trials
- Refresh our knowledge on current best practice



## International clinical trials-Challenges

#### Infrastructure & communication

- Language barriers
- Translation & verification of docs

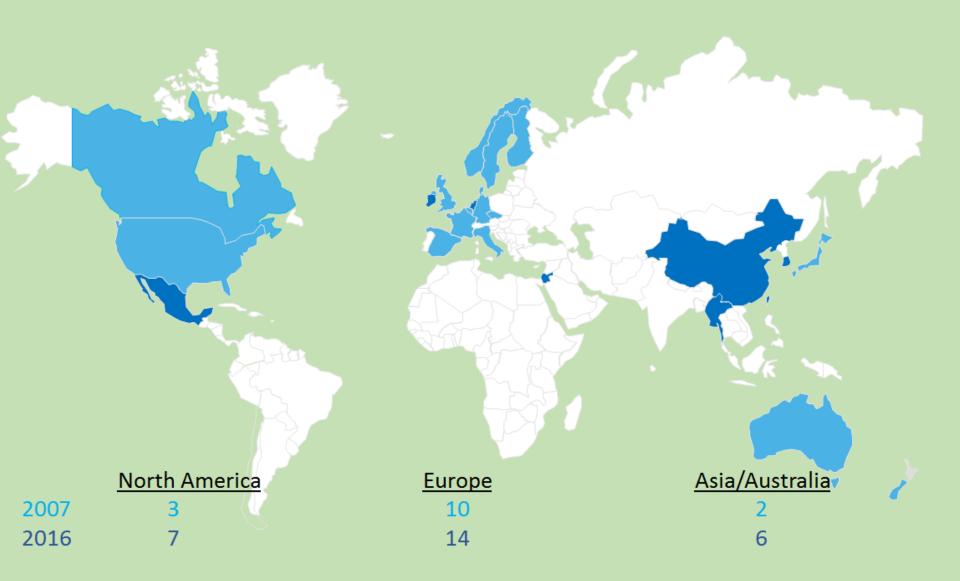
#### Contract negotiations

- Insurance & indemnification
- Provision to cover standard of care treatment

#### time

- Regulatory approvals
- Impact on accrual targets
- cost

## GCIG: Then and Now



## GCIG: 27 Groups

