



# GYNECOLOGIC CANCER INTERGROUP



An Organization of International Cooperative  
Groups for Clinical Trials in Gynecologic Cancers



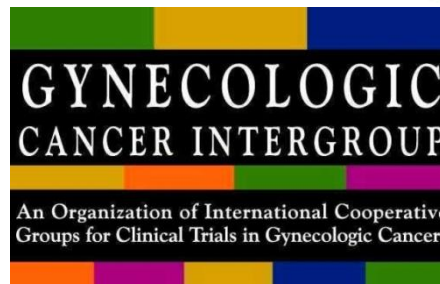


**A RANDOMIZED TRIAL COMPARING RADICAL  
HYSTERECTOMY AND PELVIC NODE DISSECTION  
VS SIMPLE HYSTERECTOMY AND PELVIC NODE  
DISSECTION IN PATIENTS WITH LOW-RISK,  
EARLY- STAGE CERVICAL CANCER**

**A Gynecologic Cancer Intergroup (GCIIG) Trial led by the CCTG**

**GCIIG Trial Designation: The **SHAPE** Trial  
CCTG Protocol Number: **CX.5****

**Chair: Marie Plante**



# Trial Schema

Low-risk cervical cancer as defined by:

- squamous cell, adenocarcinoma, adenosquamous carcinoma
- Stage **IA2** and modified **IB1**
- < 10mm SI on LEEP/cone
- < 50% stromal invasion on MRI
- max dimension of **≤ 20 mm** on MRI
- Grade 1-3 or not assessable

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ARM 1 (Control)  
Radical Hysterectomy\*

Arm 2 (Experimental)  
Simple Hysterectomy\*

→ → Pelvic relapse

\* Regardless of treatment assignment, surgery will include pelvic lymph node dissection with optional sentinel lymph node (SN) mapping. If SN mapping is to be done, the mode is optional, but the laparoscopic approach is preferred.

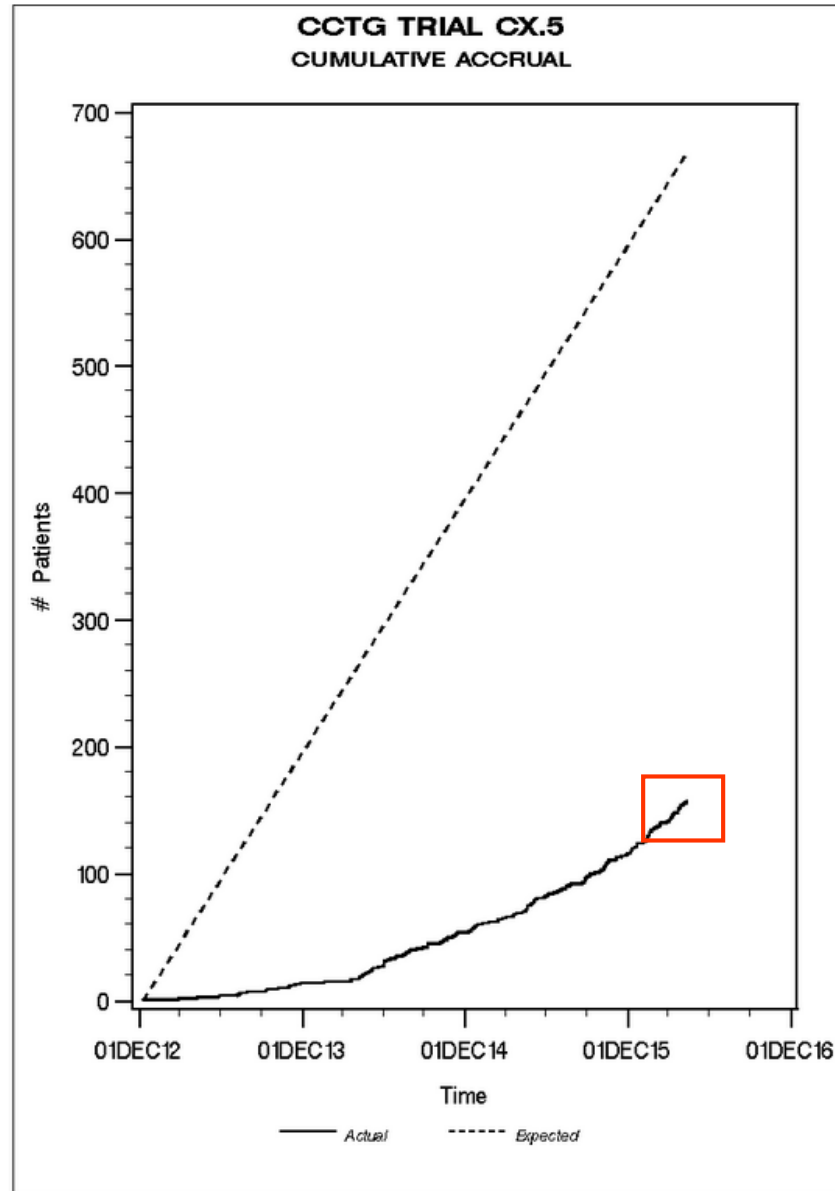
Planned sample size: **700** (non-inferiority at 0.05 level with 80% power)

# Current Status

Country	# Sites Activated
Canada	17
France	30
South Korea	1
The Netherlands	5
Belgium	8
Austria	7
Ireland	1
United Kingdom	16
China	1
<b>Total</b>	<b>86</b>

Country	# Patients Accrued
Canada	84
France	18
South Korea	7
The Netherlands	12
Belgium	11
Austria	7
Ireland	4
United Kingdom	12
China	2
<b>Total</b>	<b>157</b>

# Current Status



# Summary

- We are reaching nearly **25%** of target accrual
- We look forward to the contribution of **Moscow**
- We are looking at non-GCIG centers (CCRN initiative)
  - South America, Asia ?

**Stage IB1 (2-4 cm) Cervical cancer treated  
with Neoadjuvant chemotherapy followed by  
fertility Sparing Surgery (CoNteSSa)**

**Marie Plante (CCTG)**

**Jeffrey Goh & Vivek Arora (ANZGOG)**



NCIC Clinical Trials Group  
NCIC Groupe des essais cliniques



# Introduction

Trachelectomy is now a recognized treatment option for young women with early-stage cervical cancer and had been mostly validated for lesions **< 2 cm (NCCN)**

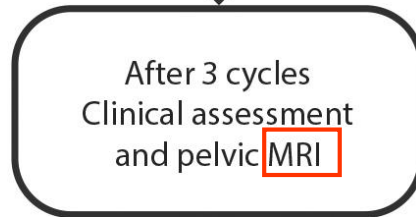
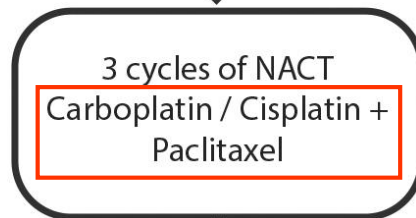
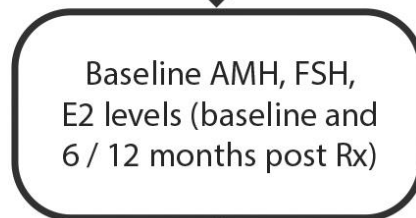
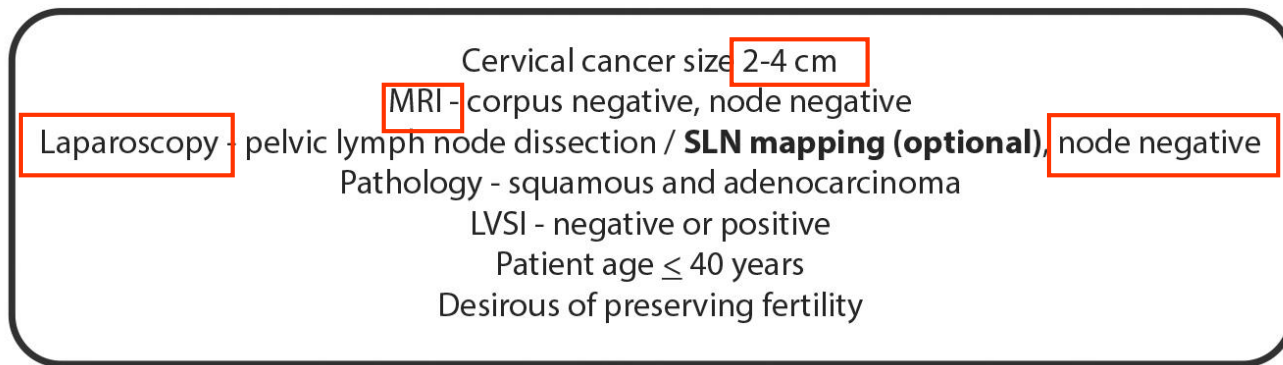
Little data regarding the optimal management of young women with lesions **> 2 cm** who wish to preserve fertility

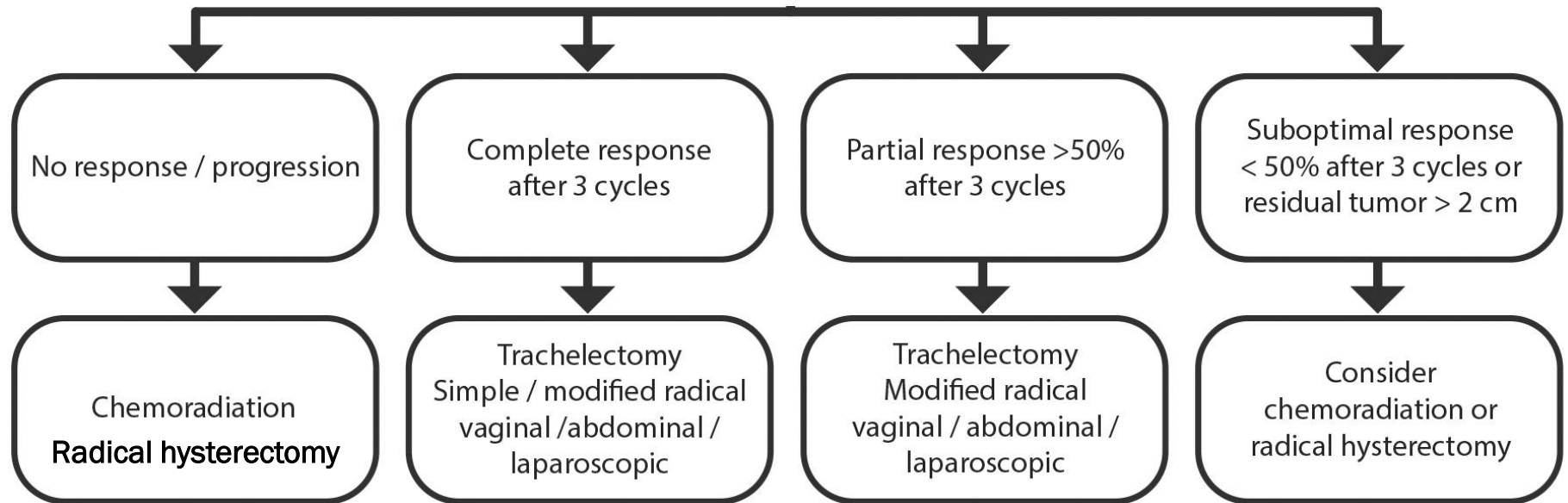


# Specific Hypothesis

**Neoadjuvant chemotherapy (NACT) in node-negative women with stage IB1 (2-4 cm) cervical cancer will enable**

- **fertility preserving surgery**
- **without compromise in tumour control in good chemo-responders**





Adjuvant chemoradiation  
(or radical hysterectomy)  
Positive margins  
Stromal involvement in outer 1 / 2  
≥ 5 mm stromal invasion  
**< 10 mm margin**



# Outcome measures

- **Primary end point**
- **Successful fertility preservation defined as intact uterine corpus with no adjuvant XRT**
- **Secondary end points**
- **Response rates to chemotherapy**
- **Toxicity**
- **Proportion requiring trimodality treatment**
- **QoL indices**
- **3 and 5 year disease free survival**
- **Ovarian function indices**

# Statistics and design

Single arm **phase-2** type of study (**75 patients**)

Two statistical issues

- **Fertility preservation** (realistically 50-60%)
  - assuming a 30% suboptimal response to NACT
  - assuming a 10-20% hi-risk features in the trachelectomy specimen requiring rad hyst or RT
- **Safety monitoring guidelines**
  - DSMC requirements
  - based on literature: relapse rates for standard
  - based on accrual

# Feasibility

- This study is **doable** within the GCIG
- Already established a large international and successful collaboration with numerous groups through SHAPE
- Great interest for this study concept
- **We need strong support**
  - **accrual and funding from all interested groups**

# Contessa

- **Presented to CCTG Executive Dec 2015**
  - **Issues of feasibility (accrual)**
  - **Issues of safety of NACT**
- **Plan to resubmit to CCTG Executive in **June 2016** for approval and consideration of funding**