



**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 (GCIg) Trial led by the CCTG

**GCIg 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.

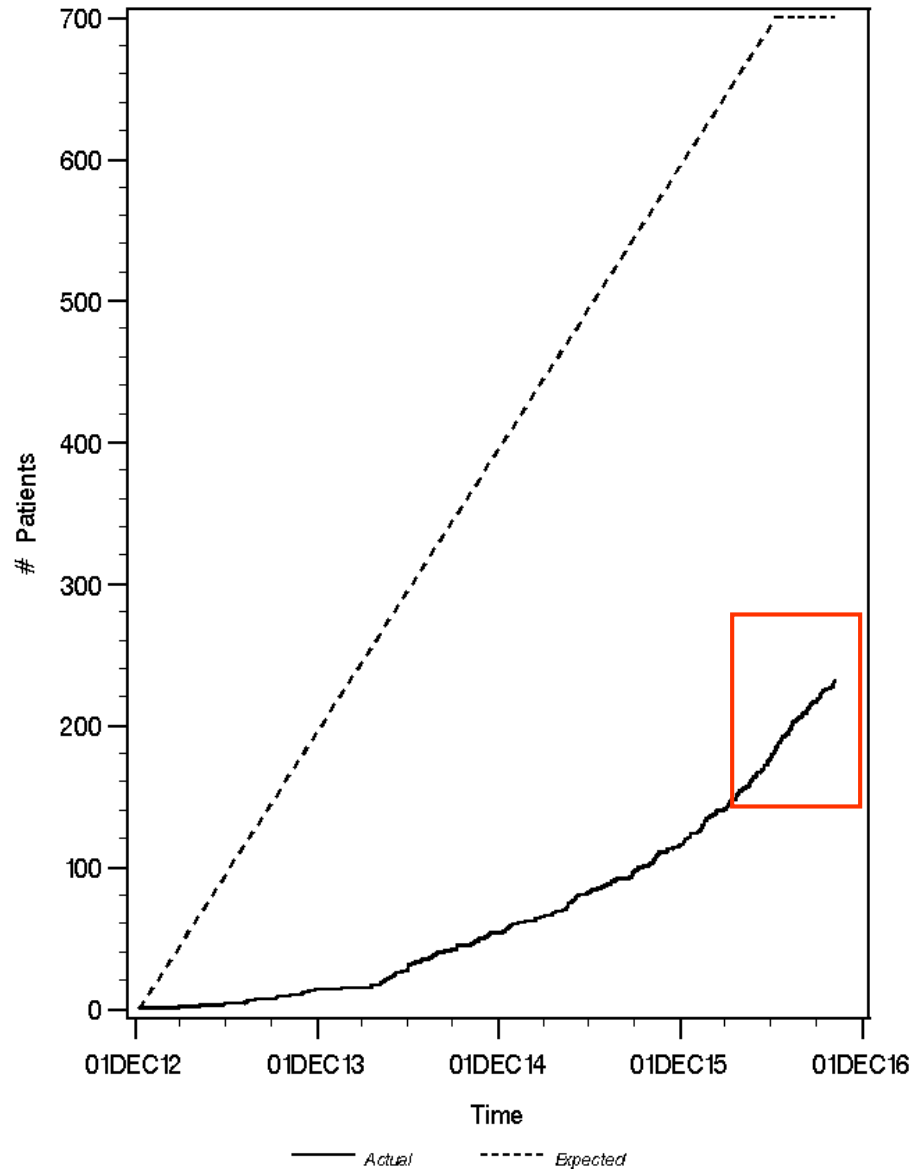
Planned sample size: **700** (non-inferiority at 0.05 level with 80% power)

Current Status

Country	# Sites Activated
Canada	16
France	33
South Korea	1
The Netherlands	7
Belgium	10
Austria	7
Ireland	1
United Kingdom	20
China	1
Total	96

Country	# Patients Accrued
Canada	106
France	34
South Korea	7
The Netherlands	27
Belgium	15
Austria	12
Ireland	7
United Kingdom	23
China	2
Total	233 (33%)

Current Status



Summary

- We have reached **33%** of total accrual
- The Herten Moscow Scientific Research Institute of Oncology has recently activated the SHAPE study
- Working towards activating centers in South America via the GCIG CCRN initiative