



**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.

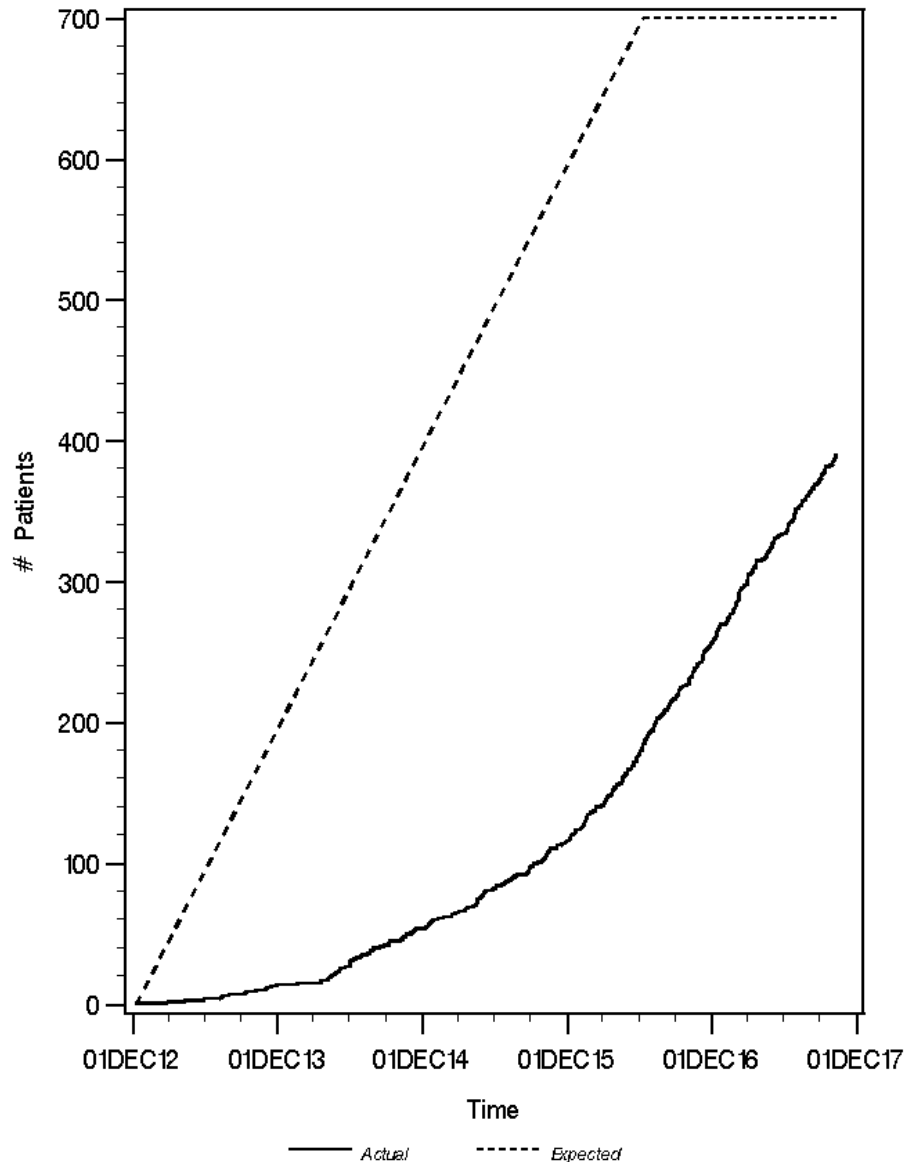
Planned sample size: **700** (non-inferiority at 0.05 level with 80% power)

Current Status

Country	# Sites Activated
Canada	17
France	33
United Kingdom	23
Belgium	8
The Netherlands	7
Austria	7
South Korea	3
Ireland	1
China	1
Russia	1
Germany	1
Total	101

Country	# Patients Accrued
Canada	133
France	74
United Kingdom	56
The Netherlands	53
Belgium	29
Austria	21
Ireland	10
South Korea	10
China	2
Russia	2
Germany	0
Total	390

Current Status



- We have reached **56%** of total accrual
- Accrual Rate for past 12 months = **13 pts/month**
- The first AGO Germany site was activated on Sept. 17!
- We hope to be able to activate two CCRN sites in **Brazil** in Q1 of 2018.