



**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.

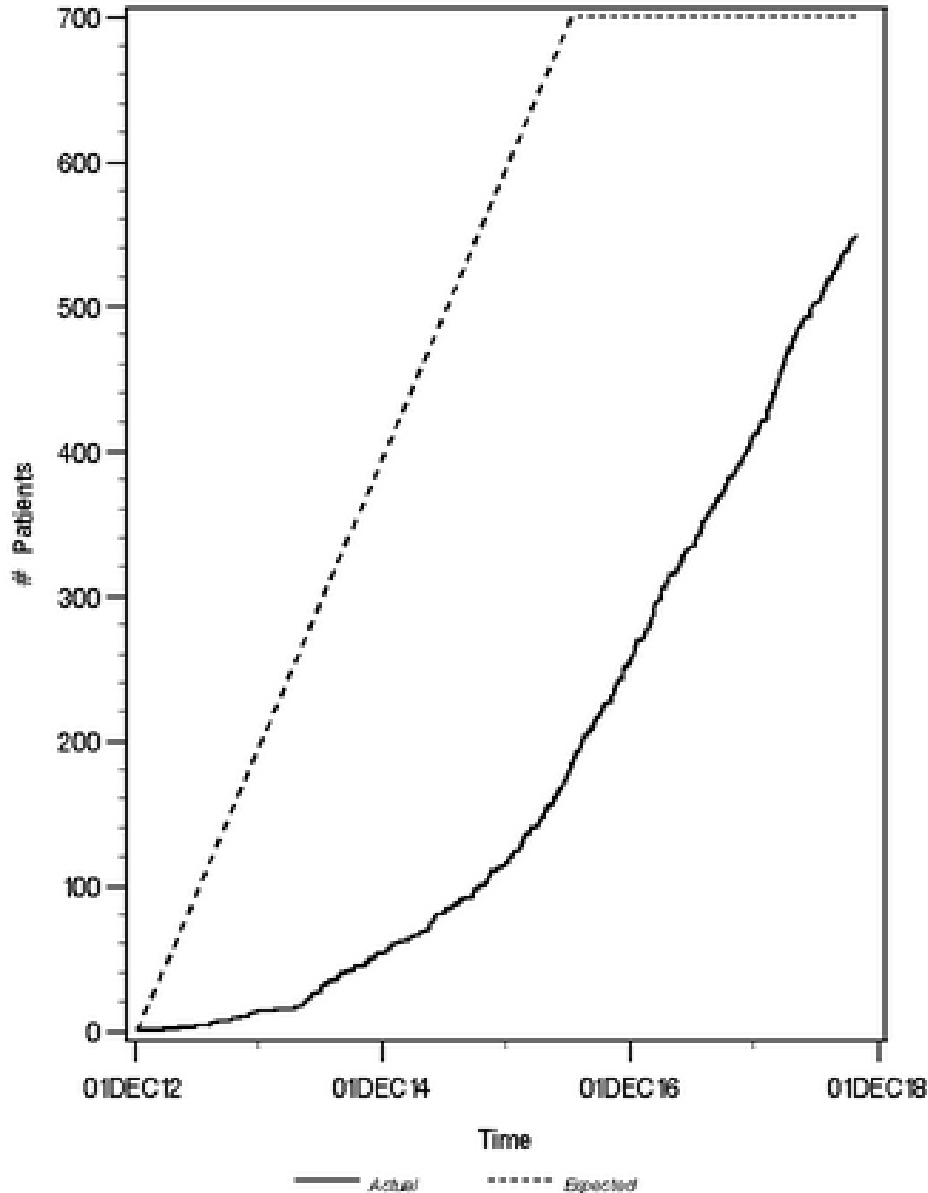
Planned sample size: **700** (non-inferiority at 0.05 level with 80% power)

# Current Status

Country	# Sites Activated
Canada	20
France	33
The Netherlands	7
UK	25
Belgium	10
Austria	7
Germany	21
Ireland	1
South Korea	3
Norway	1
Russia	1
China	1
<b>Total</b>	<b>130</b>

Country	# Patients Accrued
Canada	160
France	102
The Netherlands	84
UK	81
Belgium	32
Germany	26
Austria	24
South Korea	15
Ireland	12
Norway	9
Russia	2
China	2
<b>Total</b>	<b>549</b>

# Current Status



- We have reached **78.4%** of total accrual
- We hope to be able to activate two CCRN sites in Brazil in Q4 of 2018.
- It is our current estimation that accrual will continue until Q3 2019.