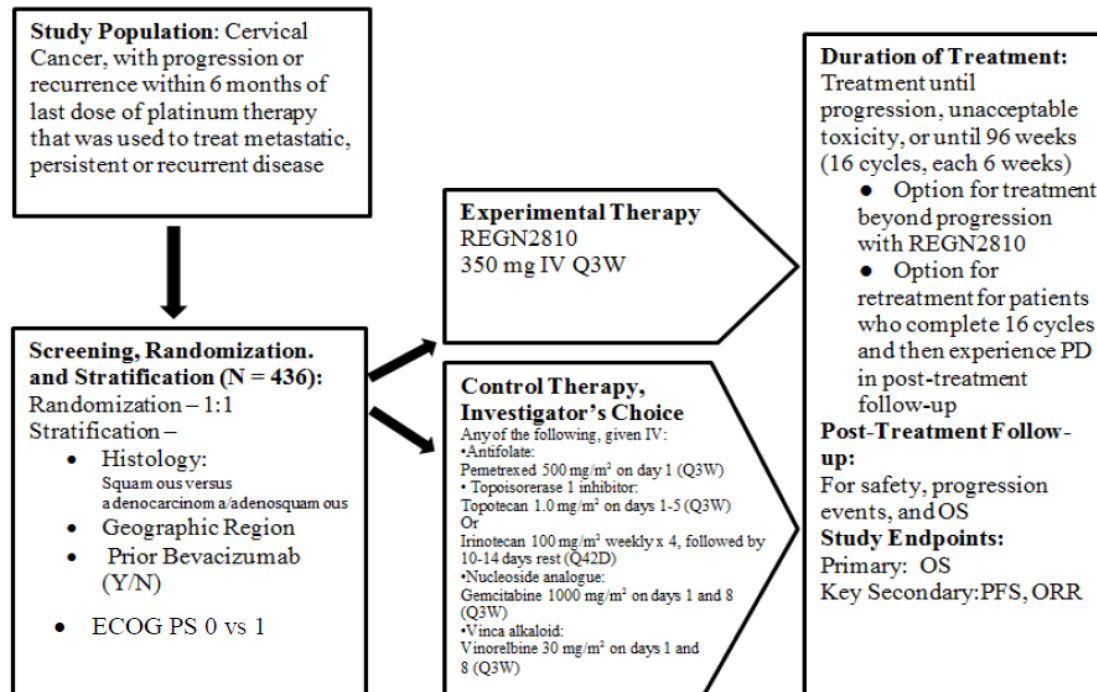


# Empower Cervical 1: R2810-ONC-1676/GOG-3016/ENGOT CX9/GEICO 72-C GCIIG Meeting

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# Empower Cervical 1: Study Design

An Open Label, Randomized, Phase 3 Clinical Trial of REGN2810 Versus Therapy of Investigator's Choice Chemotherapy in Recurrent or Metastatic Platinum-Refractory Cervical Carcinoma Sponsored by Regeneron Pharmaceuticals



# Empower Cervical 1 Review

1. Participant Groups / Countries
2. Sample Size: Recruitment update
3. ENGOT Groups Study Timelines

# Empower Cervical 1 Review

## ENGOT Participant Groups / Countries

<b>ENGOT Lead Group:</b>	<b>GEICO (Spain), PI Dr. Ana Oaknin</b>
BGOG (Belgium)	PGOG (Poland)
MaNGO (Italy)	HeCOG (Greece)
MITO (Italy)	NCRI (UK)

# Empower Cervical 1 Review

## ENGOT Groups' Participation

▪ <b>GEICO:</b>	10 sites, 40 patients	PI: Dr. Ana Oaknin
▪ <b>PGOG:</b>	03 sites, 12 patients	PI: Dr. Radoslaw Madry*
▪ <b>BGOG:</b>	06 sites, 24 patients	PI: Dr. Ignace Vergote
▪ <b>MaNGO:</b>	05 sites, 20 patients	PI: Dr. Domenica Lorusso*
▪ <b>MITO:</b>	06 sites, 24 patients	PI: Dr. Domenica Lorusso
▪ <b>HeCOG:</b>	06 sites, 24 patients	PI: Dr. Flora Zagouri
▪ <b>NCRI:</b>	06 sites, 24 patients	PI: Dr. Azmat Sadozye

42 sites, 168 patients

\* PGOG's PI needs to confirm his participation in the Study

\* Italy (MITO&MANGO) will have a common PI.

# Empower Cervical 1: Recruitment update:

## Trial Sample Size: 436 patients

Global numbers	Total Screened subjects	Total Randomized	Total Dosed subjects	Total SF
TOTAL	155	113	104	34

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# Empower Cervical 1: Recruitment update

## Countries' Breakdown

Global numbers	Initiated sites	Active sites	Total Screened subjects	Total Randomized	Total Dosed subjects	Total SF
<b>TOTAL</b>	<b>73</b>	<b>50</b>	<b>155</b>	<b>113</b>	<b>104</b>	<b>34</b>
US	33	10	31	21	19	10
Russia	8	8	4	3	3	0
Canada	6	6	22	14	13	6
Australia	6	6	16	12	12	4
South Korea	6	6	36	27	25	7
Spain	5	5	9	8	6	0
Poland	5	5	25	18	18	5
Taiwan	4	4	12	10	8	2
Brazil	0	0	0	0	0	0
Japan	0	0	0	0	0	0

ENGOT numbers	Initiated ENGOT sites	Active ENGOT sites	Total Screened subjects	Total Randomized	Total Dosed subjects	Total SF
<b>TOTAL</b>	<b>8/42</b>	<b>8</b>	<b>30</b>	<b>22</b>	<b>20</b>	<b>5</b>
Spain	5/10	5	9	8	6	0
Poland	3/3	3	21	14	14	5
UK	0	0	0	0	0	0
Italy	0	0	0	0	0	0
Belgium	0	0	0	0	0	0
Greece	0	0	0	0	0	0



# Empower Cervical 1 Review

## ENGOT Groups Study Timelines

GROUP	Submission Planned	SIV-FPI Planned
<b>GEICO</b> Dr. Ana Oaknin	Amendment for news sites addition planned for Nov 2018	1st SIV-FPI for the new sites planned in January / February 2019
<b>BGOG</b> Dr. Ignace Vergote	Submission planned for November 2018	1st SIV-FPI planned in January / February 2019
<b>MaNGO</b> Dr. Domenica Lorusso	Submission planned for November 2018	1st SIV-FPI planned in February / March 2019
<b>MITO</b> Dr. Domenica Lorusso	Submission planned for November 2018	1st SIV-FPI planned in February / March 2019
<b>HeCOG</b> Dr. Flora Zagouri	Submission planned for January 2019	1st SIV planned in April / May 2019
<b>NCRI</b> Dr. Azmat Sadozye	Submission already done: 31Aug2018	1st SIV-FPI planned in January / February 2019