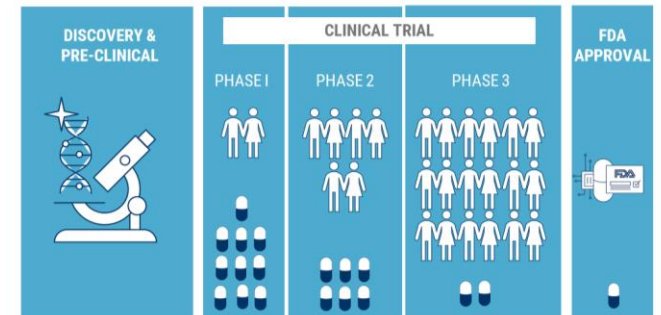


## ENGAGe-ENGOT Clinical Trials Project

 Bringing a drug to market is a drawn-out process



CBINSIGHTS

### Why was the PRIMA trial chosen?

- The 3 webinars from September 2, 2019
  - Terminology in a clinical trial
  - Study methodology – single arm, dual arm, prospective, retrospective
  - Informed consent, PRO (Patient Reported Outcome), side effects etc.
- Now with an example of an actual trial (abstract of the PRIMA trial sent to you).
- Understanding a clinical trial regardless of the disease
- The various steps in a trial and the terminology in a study
- Presentation of the trial by the prime investigator Prof. Antonio González Martín

## ENGAGe-ENGOT Clinical Trials Project

### Birthe Lemley working with Prof. Jalid Sehouli from ENGOT

#### The working group:

- Charo Hierro, president of ASACO, Spain
- Maria Papageorgiou, president of K.E.F.I. Greece
- Janni Zmylon, member of KIU Denmark

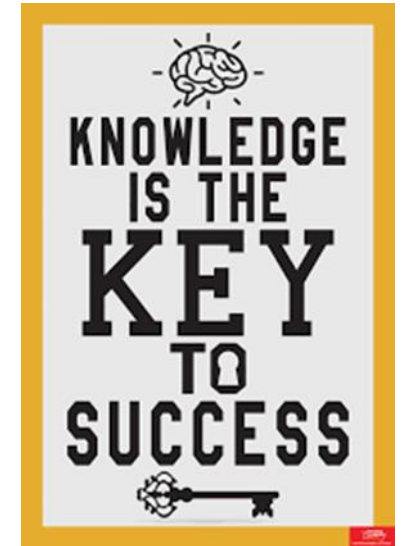


**18 patients from 10 different European countries representing the diseases cervical cancer, endometrial cancer, ovarian cancer, and rare cancers.**

## ENGAGe-ENGOT Clinical Trials Project

### Teaching material so far:

- **3 Webinars on September 2, 2019**
- **Report and summary of the webinars called the ‘Study book’**
- **Access to SoA presentations from December 14-16, 2020. Jan 31, Feb 28.**
- **Questions to SoA presentations**
- **Answers to the questions (7 received)**
- **5 Webinars in the spring of 2021 – example the PRIMA trial.**



## ENGAGe-ENGOT Clinical Trials Project

### Course certificate

Advertise on ESGO ENGAGE and ENGOT websites that such a group of patients exist at ENGAGe

Who can use such a service?

- ESGO, ENGOT, EORTC and other organisations
- HTA (Health Technology Assessment) bodies
- EMA
- Foundations as a 'patient reviewer'
- Pharmaceutical companies



## ENGAGe-ENGOT Clinical Trials Project

### Patient perspective and insight on:

- Method of treatment – IV, capsules, tablets etc.
- Questionnaires on QoL and side effects
- Patient Reported Outcome (PRO)

### Instrumental in:

- Spreading the word about recruitment
- Dissemination of the outcome of the trial
- Approval of the drug in the various countries
- Cross-border participation in clinical studies?

