How to open a clinical trial in Ireland

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cancer trials ireland

Unmet clinical need…

USA 2014

AstraZeneca

AstraZeneca Websites | Global site

AstraZeneca in the United States | Sustainability | Medicines | Careers | Media

LYNPARZA™ approved by the US Food and Drug Administration for the treatment of advanced ovarian cancer in patients with germline BRCA-mutations

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SGO

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All Resources

SGO CLINICAL PRACTICE STATEMENT: GENETIC TESTING FOR OVARIAN CANCER (SGO, OCTOBER 2014)

RECOMMENDATIONS, GENETICS, OVARIAN CANCER

Oct 1, 2014

Women diagnosed with epithelial ovarian, tubal, and peritoneal cancers should receive genetic counseling and be offered genetic testing, even in the absence of a family history.

Ireland 2014 - 2016

Irish Examiner

A sad reflection

THE announcement by Angelina Jolie that she had preventative mastectomies after genetic testing revealed she has a gene which gives her an 87% lifetime risk of developing breast cancer, has highlighted the significance of this situation for many Irish women.

TUE, 21 MAY, 2013 - 01:00

ANALYSIS ANDREW GREEN

The issue for women who may find themselves in the same position, is timely access to genetic services.

Unmet clinical need … meets fortuitous circumstances

Tumor BRACAnalysis™ CDx

Network

Links with industry/scientists

Working in a laboratory research setting

Time

Resources

Research mentor also CTI vice clinical lead

Initial steps: involve stakeholders into trial design

Draft design v1.0
- Key rationale, aims, endpoints

→ **Gauge interest**
- Informal enquiries

→ **Brainstorming meeting**
- Key stakeholders

→ **DRAFT DESIGN v2.0**

First contacts with Cancer Trials Ireland

Study proposal at DSSG

Study Concept (Part A)/ Resource Plan/Requirement (Part B) Form

Study Concept Form (Part A)

*(maximum of three pages in total for **part A**, font size 11)*

Study Title: *Please provide a title which encapsulates the objective(s) of study proposal*
Chief Investigator:
If this is a multi-modality study (e.g. radiotherapy, surgery, medical oncology), provide name(s) of potential co-Chief Investigator(s):
Interested Colleagues:
Background & Rationale: *Please provide a brief background and outline the question(s) this study will answer or the information this study will generate*
Patient Population/Key Inclusion Criteria/Accrual target *(Please comment on sample size calculation)*:
Provide an assessment of the required patient population in general with respect to the disease characteristics required for the study based on available data to support the study feasibility, e.g. numbers of patients with disease/ percentage of patients with required mutation, etc.
Clinical: Treatment of Interest (and comparator(s) if relevant): **Translational: Standard treatment**
Primary Endpoint(s):

Secondary Endpoint(s):
Translational Aspect/ Analysis:
Sample Type/ Number: *e.g. blood samples (what type), tissue, etc.; once off or longitudinal samples*
Is funding in place to support the Translational Aspect? *If Yes (please provide details) / If No (please comment on plan)*
Collaborative Nature of the study: *Please comment on any proposed collaborations aside from Cancer Trials Ireland and participating sites*
Concept Version:
International Peer Review: *I agree that this Study Concept will undergo international peer review if approved by the DSSG.*

Name (please print) _____ Signature _____ Date _____

Resource Plan/Requirement (Part B) Form

Anticipated resources required: **a) from Cancer Trials Ireland Group Central Office:** *Specify all applicable*	
Project Management (e.g. protocol development, study initiation)	
Monitoring (e.g. remote and/or on-site)	
Pharmacovigilance (SAE reporting, SUSAR/ DSUR reporting)	
Data Management (CRF development, patient registration, database management)	
Statistics (sample size calculation, study analysis)	
DSMB (specify review frequency/ timepoints)	
Translational Oversight (data, sample collection, laboratory systems)	
Other (specify)	
Is funding for above activities available? *If Yes (please provide details) / If No (please comment)*	
b) at hospital site: *Specify all applicable*	
Patient Screening, Consenting, Enrollment, Registration, Assessments	
Data Management	
Sample collection	
Other (specify)	
Is funding for per patient payments available? *If Yes (please provide details) / If No (please comment)*	

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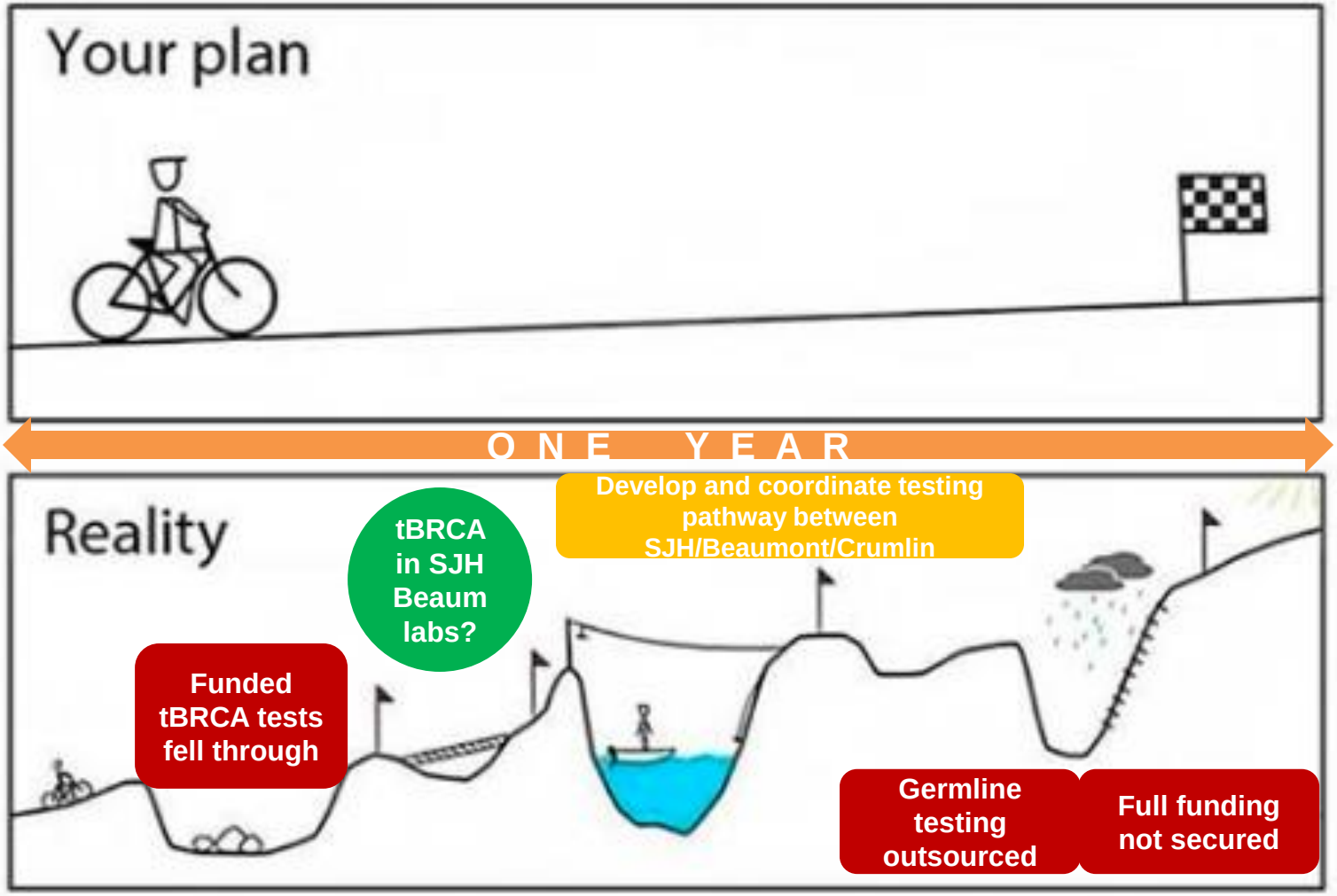
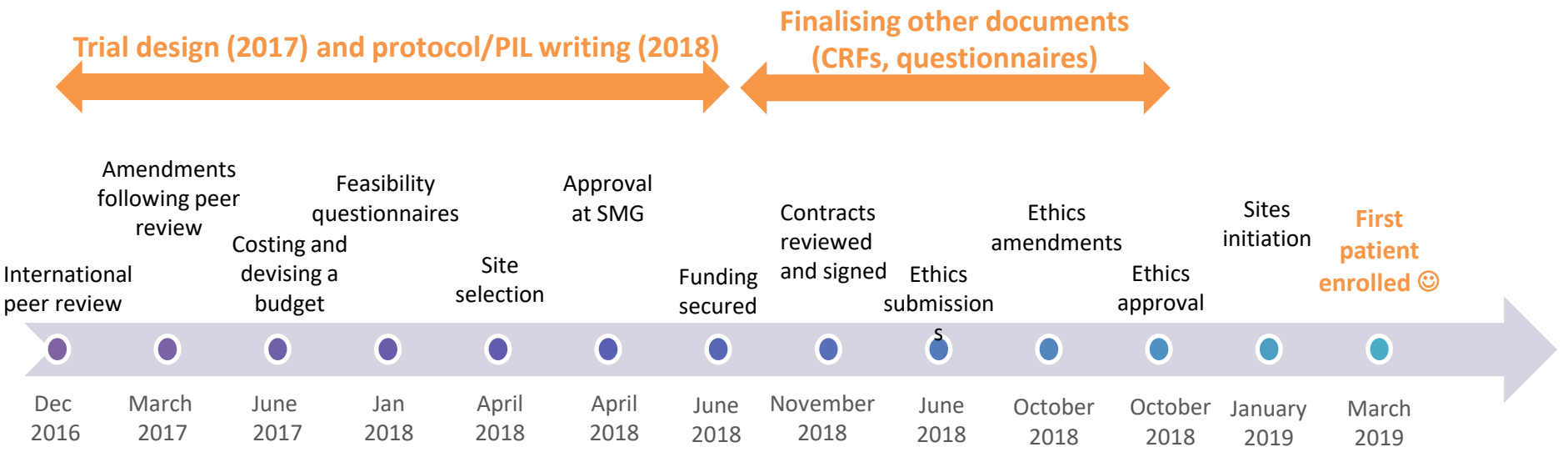
Study proposal at DSSG

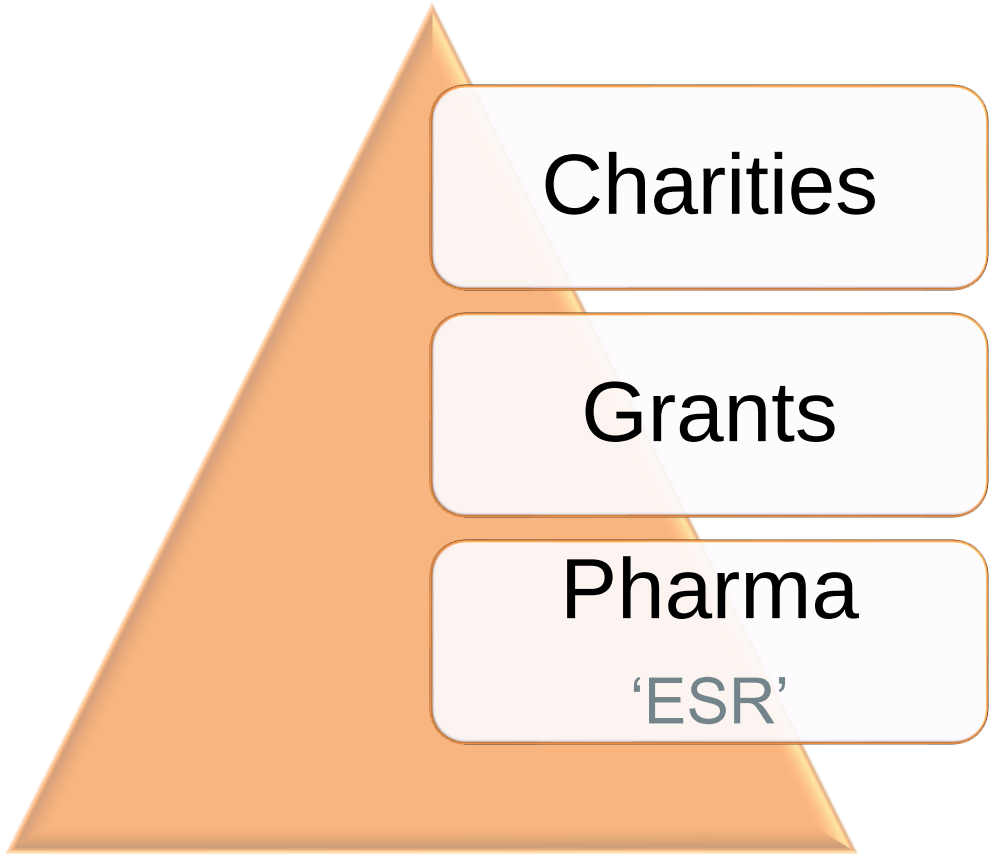
Finalising the study design



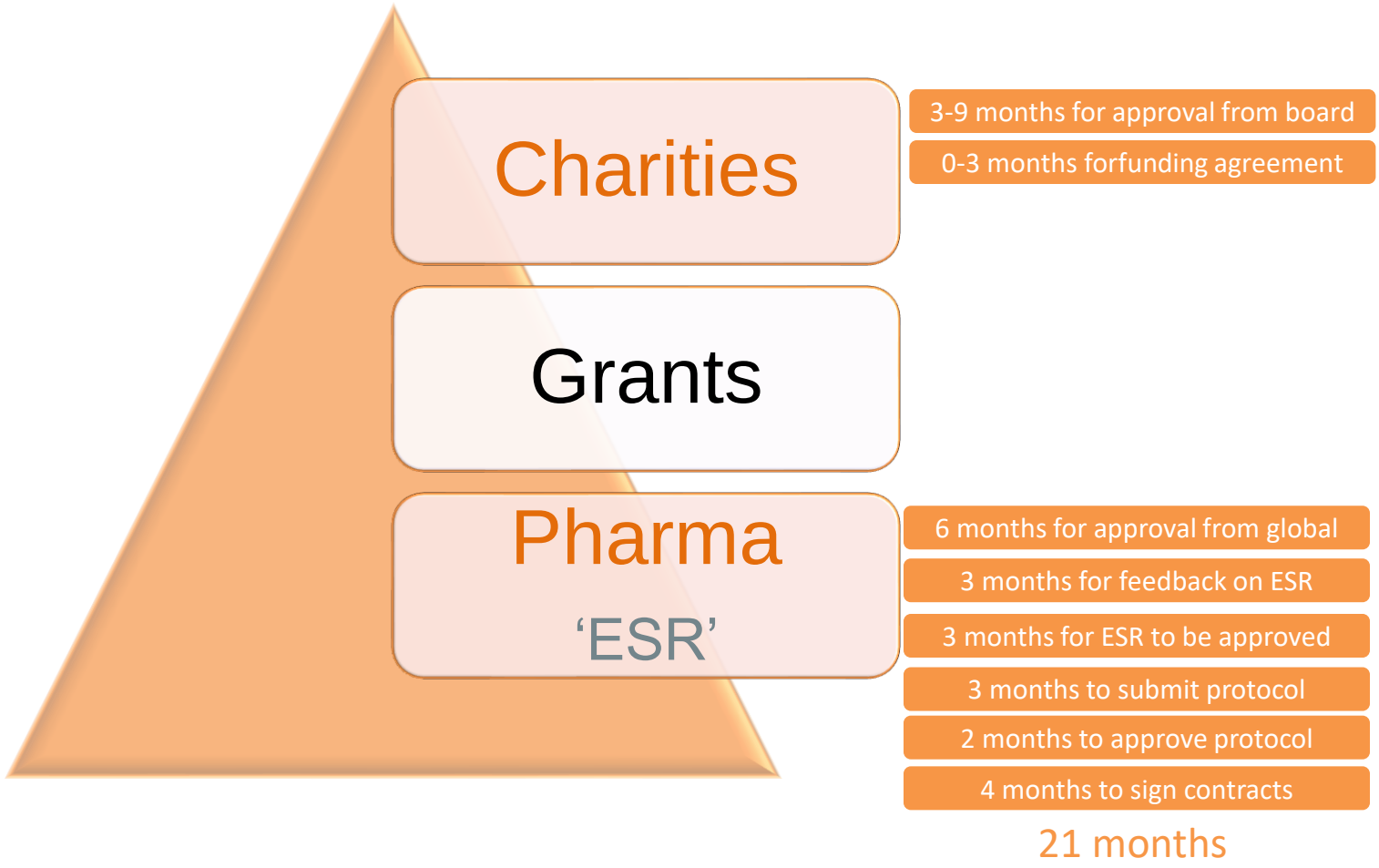
Timeline.. longer than anticipated



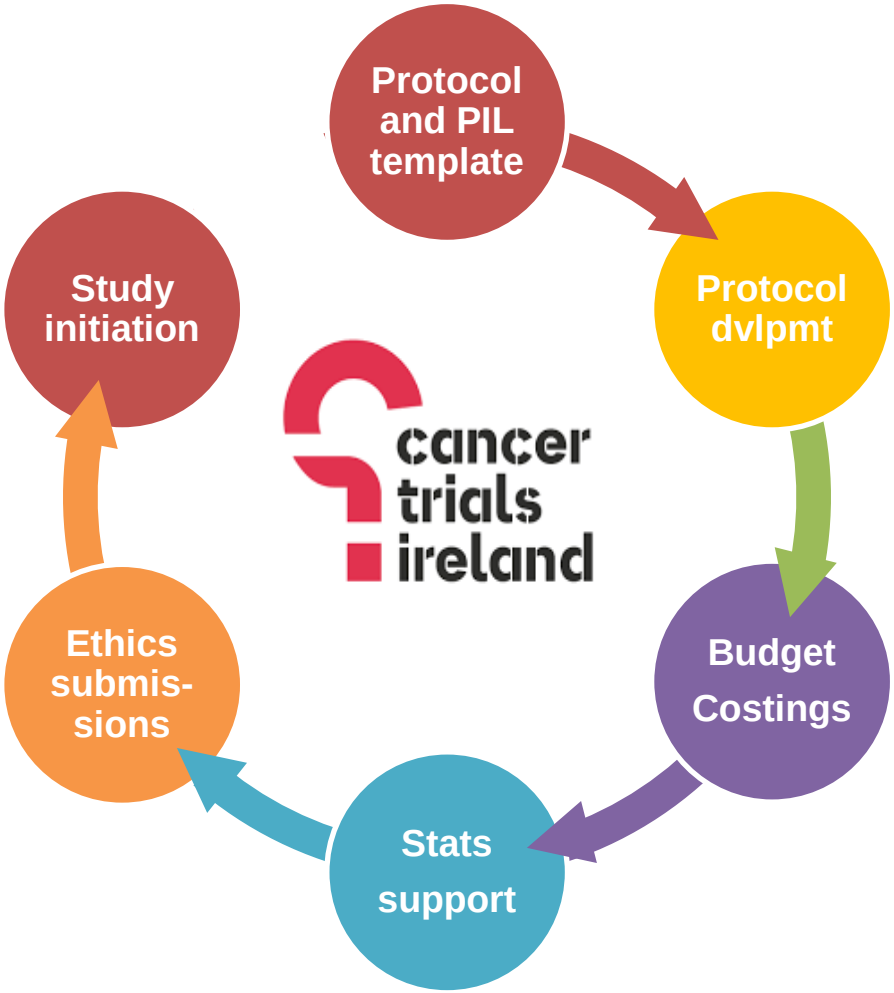
Securing funding



Securing funding



Essential facilitator and support system



Regular communication and patience

Me in the lab

Orla and Anne-Marie at CTI

Tips and treats

- Mentor/supervisor
  - Principle investigator training programme?
- Spend time upfront thinking through and designing a thorough protocol
  - Networking
  - Brainstorming
  - Ultimately time saving
- Explore all funding options (pharma, grants, charities) upfront
- Early involvement with appropriate DSSG in CTI
- Regular communication with CTI
  - From study design to initiation

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