

# Financial risks in clinical trials

March 2019

Yisrael Gewirtz



# Agenda

- 
- 01 Clinical budget planning
  - 02 Financial risks in clinical trials
  - 03 QA Budget
  - 04 Controls & Monitoring

A woman with blonde hair, wearing safety glasses and a light blue surgical mask, is shown in profile. She is holding a pipette and appears to be working in a laboratory or clinical setting. The background is blurred, showing various pieces of equipment. A purple geometric overlay is on the right side of the image.

# Clinical Budget planning

# Clinical Budget – Main Costs

Clinical

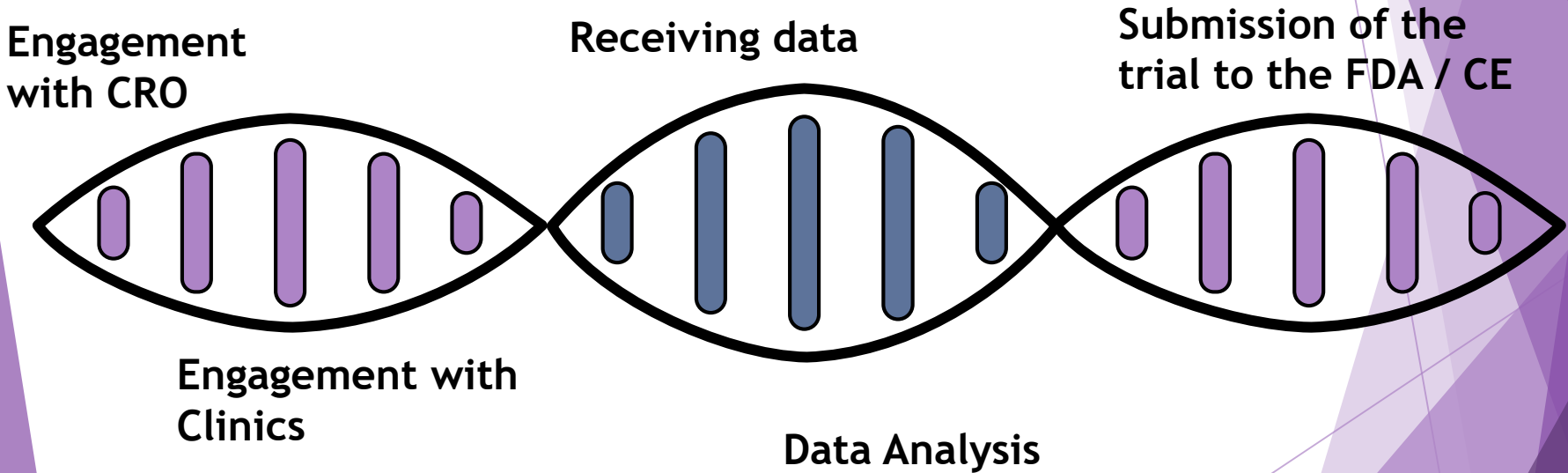
Manufacturing

Research &  
Development

General and  
Administrative



# Clinical Budget – Timeframe



# Clinical Budget planning

**Known-in-advance expenses**

**&**

**Unforeseen expenses**



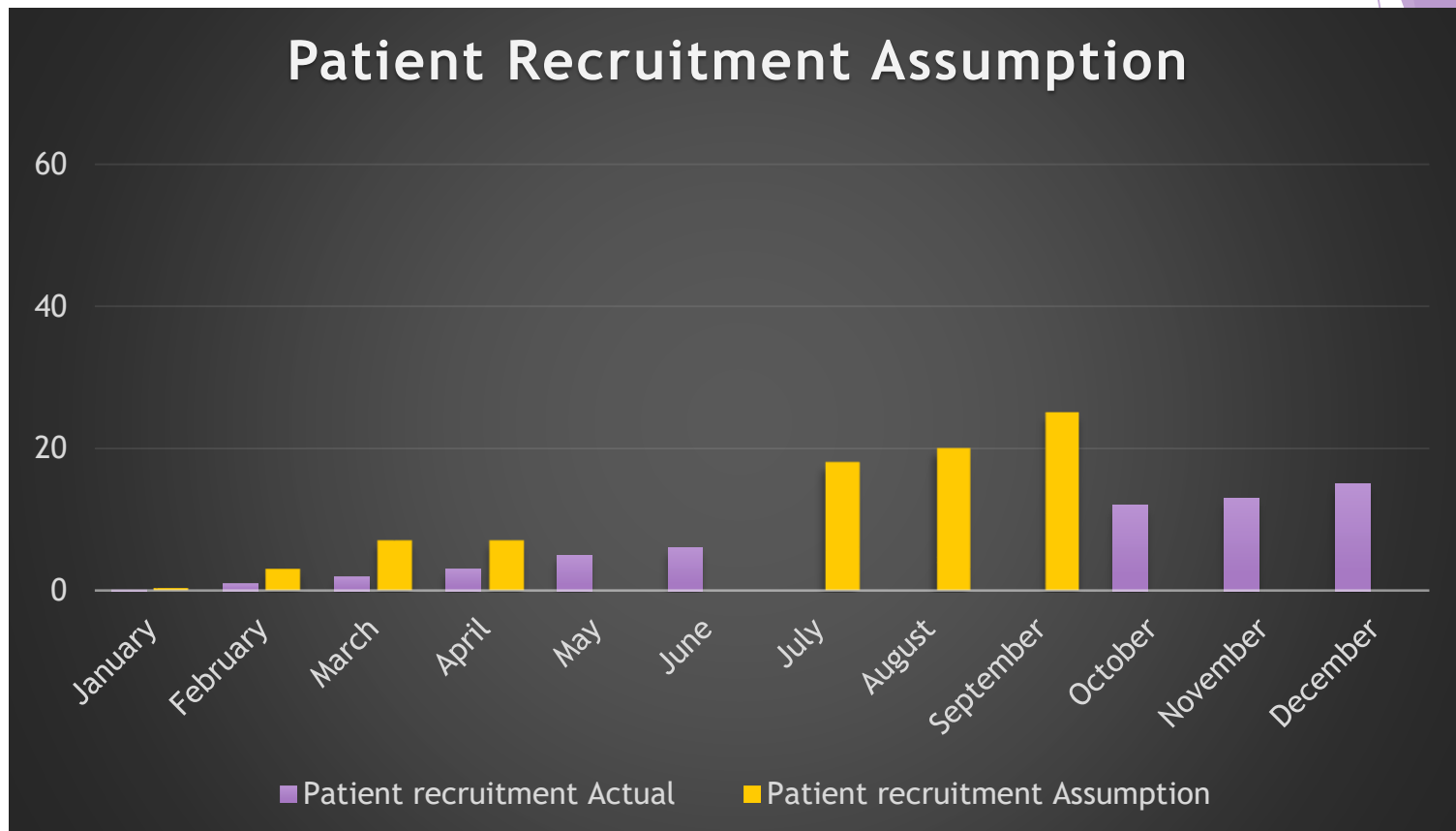
## Financial risks in clinical trials

# Financial risks in clinical trials

Delay = \$



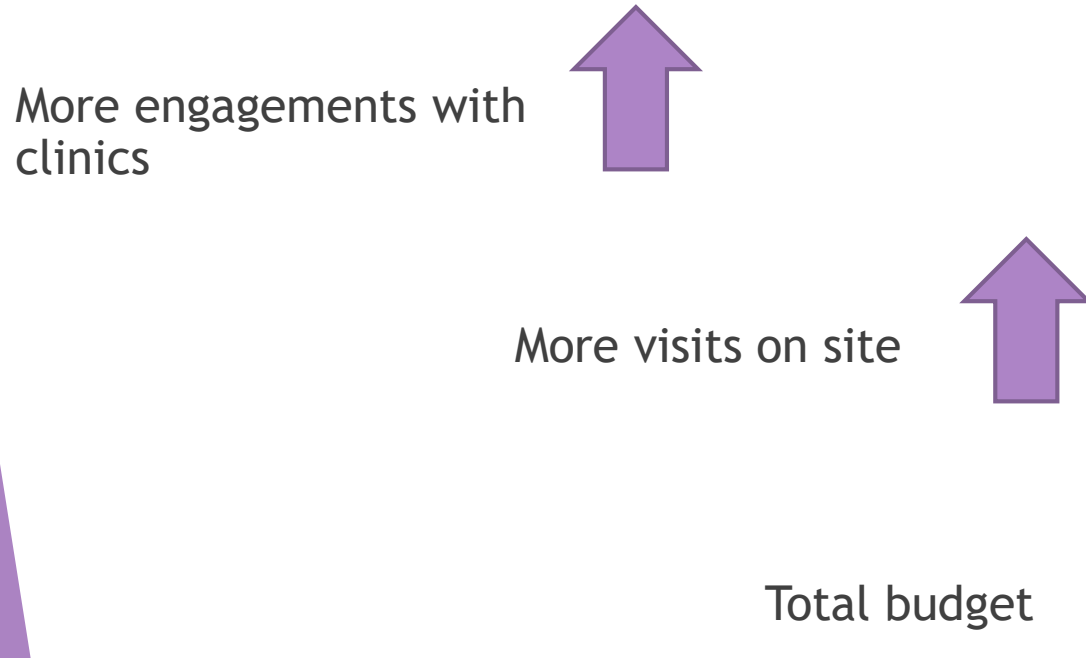
# Financial risks in clinical trials



# Financial risks in clinical trials

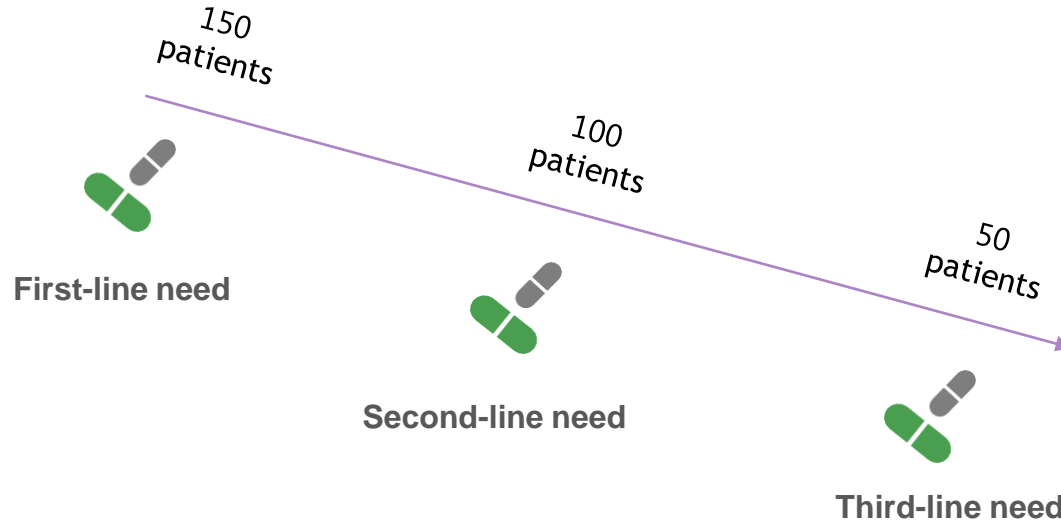
INC Research Project Costs	Unit Type	Number of Units	Cost per Unit USD (\$)	Total Cost USD (\$)
Investigator Meeting Preparation/Attendance	Meeting	1	80,000.00\$	80,000.00\$
Project Oversight	Months	2.00	1,750.00\$	3,500.00\$
Recruitment and/or Retention Materials Development	Materials	15	1,000.00\$	15,000.00\$
Internal Team Meetings	Meeting	30	200.00\$	6,000.00\$
Trip Report Review	Reports	425	500.00\$	212,500.00\$
Sponsor Teleconferences	Teleconference	130	250.00\$	32,500.00\$
Project Oversight	Months	45.00	625.00\$	28,125.00\$
Internal Team Meetings	Meeting	110	150.00\$	16,500.00\$

# Financial risks in clinical trials



# Financial risks in clinical trials

## Assumptions of the trial duration for each patient



# Financial risks in clinical trials

## Manufacturing

Shipping cost



Missing Component



KIT items defensing



A close-up, profile view of a female scientist with blonde hair, wearing a white lab coat, a blue surgical mask, and clear safety glasses. She is holding a glass pipette and appears to be working in a laboratory. The background is a blurred view of laboratory equipment. A purple geometric overlay is on the right side of the image.

# QA Budget

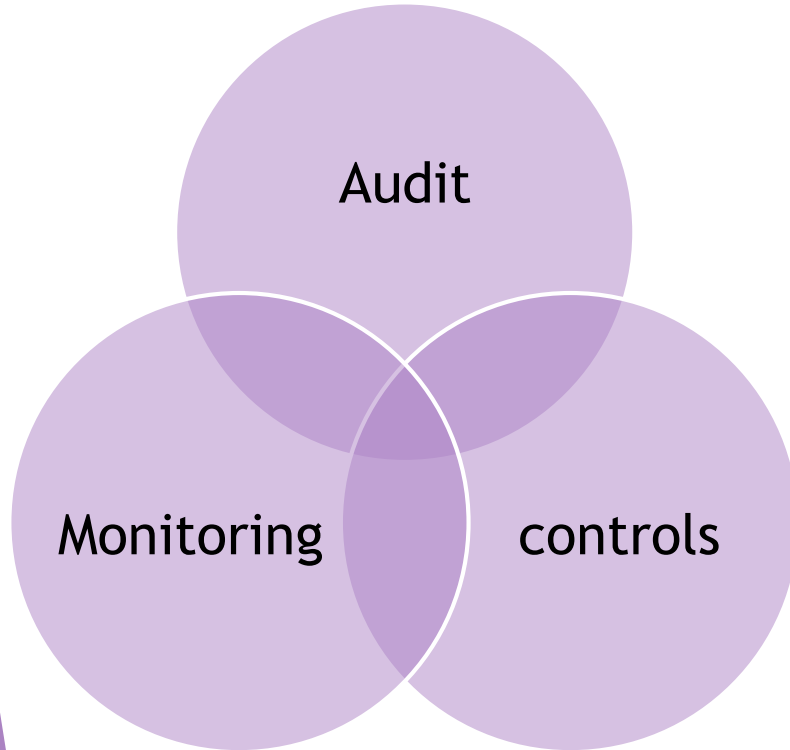
# Quality Assurance Budget

trail integrity and quality is the main objective



# Quality Assurance Budget

## Assuring high quality has its price



=

\$



# Quality Assurance Budget

Visits on site

Monitoring plan &  
CRO  
communication  
plan

Audit plan by an  
independent  
quality consultant



# Quality Assurance Budget

CT Center



Central Lab



A close-up, profile view of a female scientist in a laboratory. She is wearing a white lab coat, a blue surgical mask, and clear safety glasses. She is holding a glass pipette and appears to be working with a test tube. The background is a blurred laboratory setting with various pieces of equipment. A purple geometric overlay is on the right side of the image.

# Controls & Monitoring

# Controls & Monitoring

## Payment Approval Process

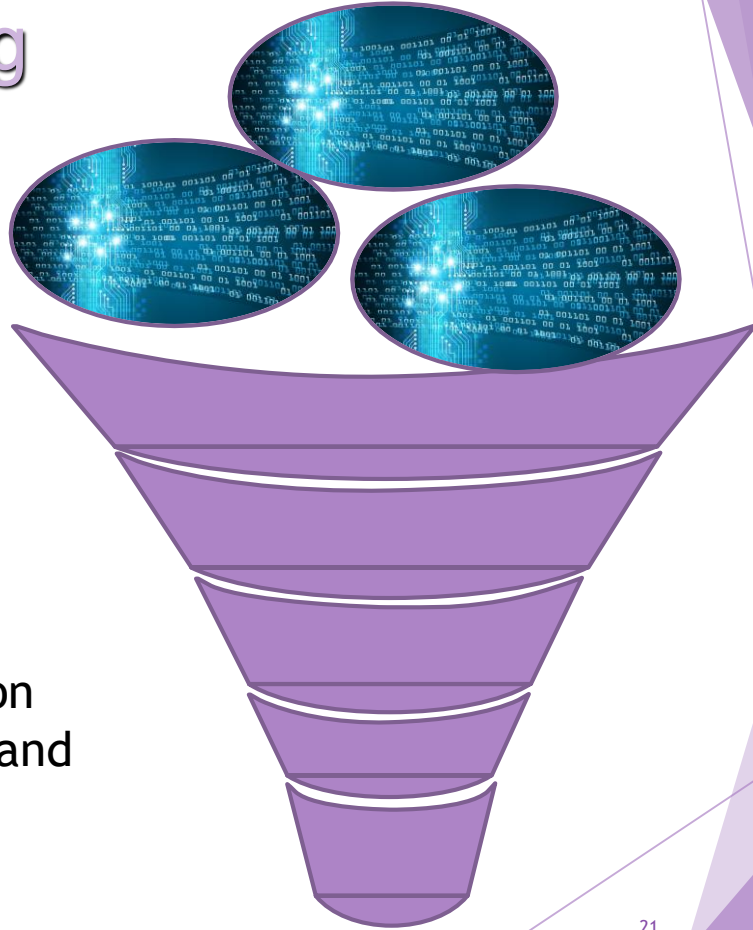


# Controls & Monitoring

Challenge - Complexity

Solution

flow of information  
between the clinic and  
faience



# Control & Monitoring

**Budget versus Actual  
controls**

**Monitoring of Invoicing  
for each budget item**

## Required controls

**Monitoring the clinics  
invoicing (in addition to  
the CRO)**

**Monitoring of  
Reimbursement (e.g. labs)**

# Thanks!

**Yisrael Gewirtz, CPA**  
**Partner**

Fahn Kanne Control Management Ltd.  
T (direct)+972 3 7106572 | T (office) +972 3 7106555  
T (mobile) +972 50 8230438 | F +972 3 7106550  
E [Yisrael.Gewirtz@il.gt.com](mailto:Yisrael.Gewirtz@il.gt.com) | W [www.gtfk.co.il](http://www.gtfk.co.il)

