

Financial Risks in Clinical Trials


July 2022

Yisrael Gewirtz, CPA

Partner



Agenda Style

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



Clinical Budget Planning

Clinical budget – main costs

Clinical

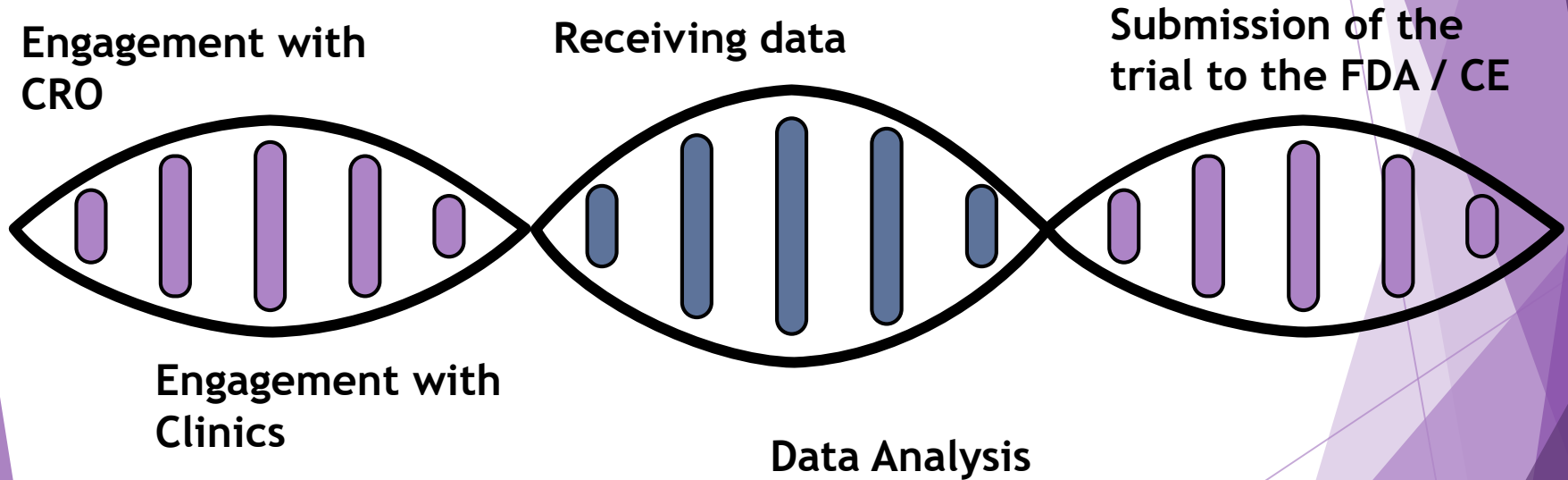
Manufacturing

Research &
Development

General &
Administrative



Clinical budget – timeframe



Clinical budget planning

Known-in-advance expenses

&

Unforeseen expenses

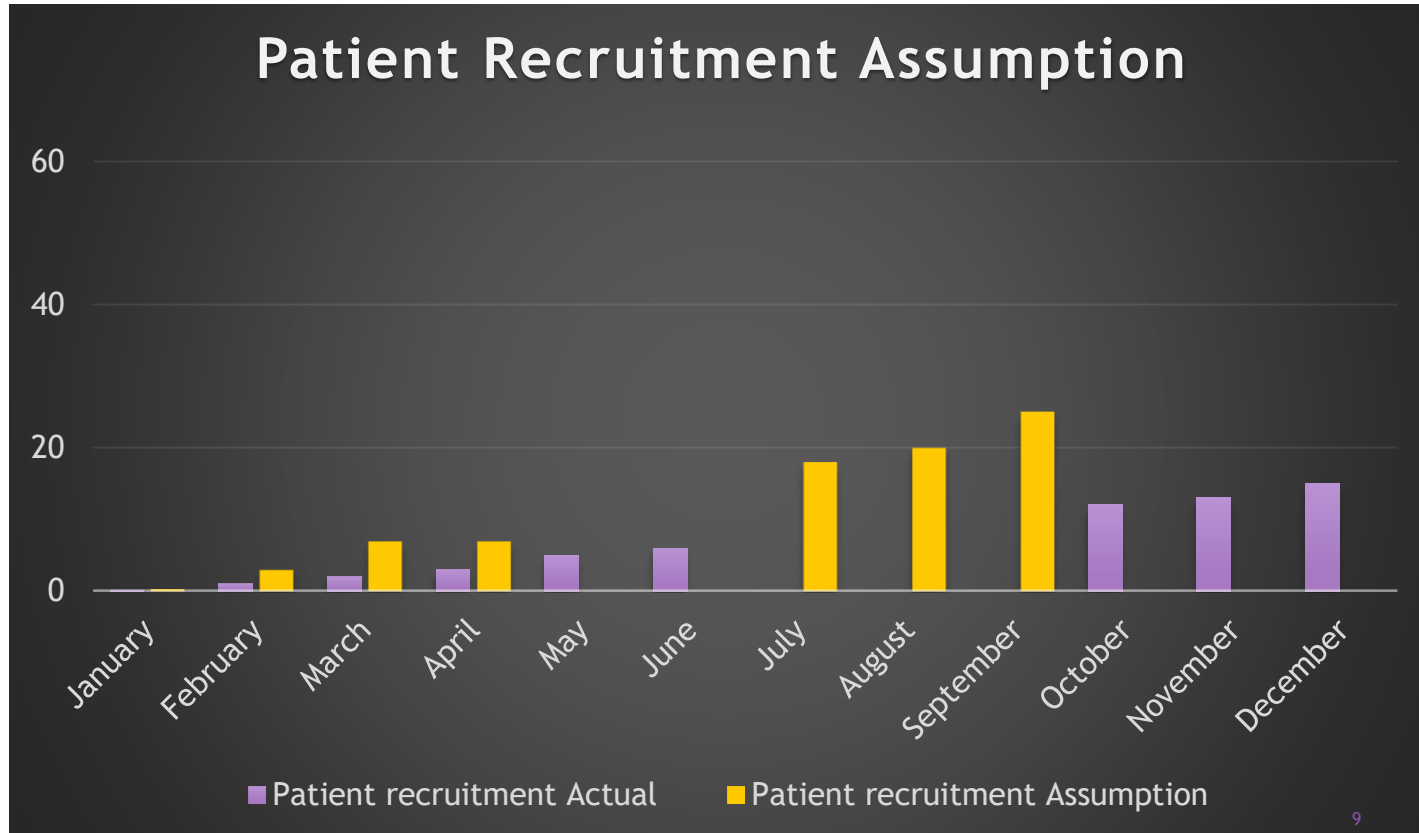


Financial Risks in Clinical Trials

Financial risks in clinical trials

Delay = \$

Financial risks in clinical trials



‘Agile Clinical Trials’ Promise to Improve Patient Recruitment and Retention



When **Elisa Cascade**, chief product officer for Science 37, looks to the future, she’s excited about what she sees.

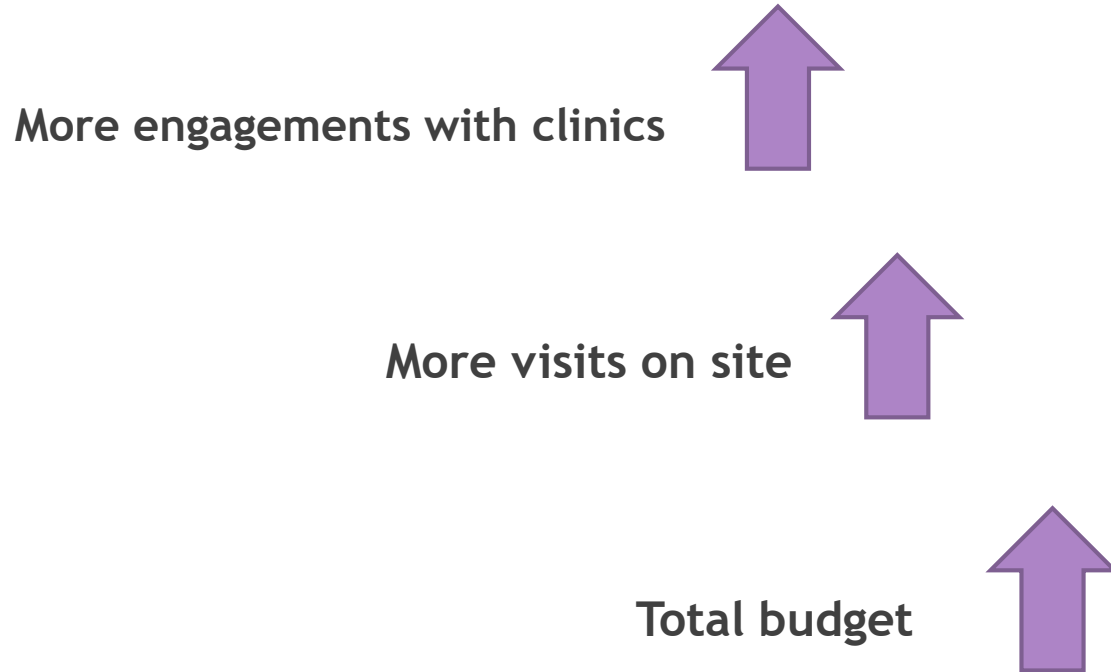


- ▶ “In the old model, patient recruitment was the leaky funnel” slowing clinical trials and dissipating effectiveness, Cascade says. Studies have shown the average person is willing to travel about 30 minutes each way to regularly participate in a trial, she notes.
- ▶ However, Cascade is excited about the rise of “**agile clinical trials**” which at their best can mesh remote aspects of decentralized clinical trials (DCTs) with direct patient care to widen the participation tent and improve diversity.

Financial risks in clinical trials

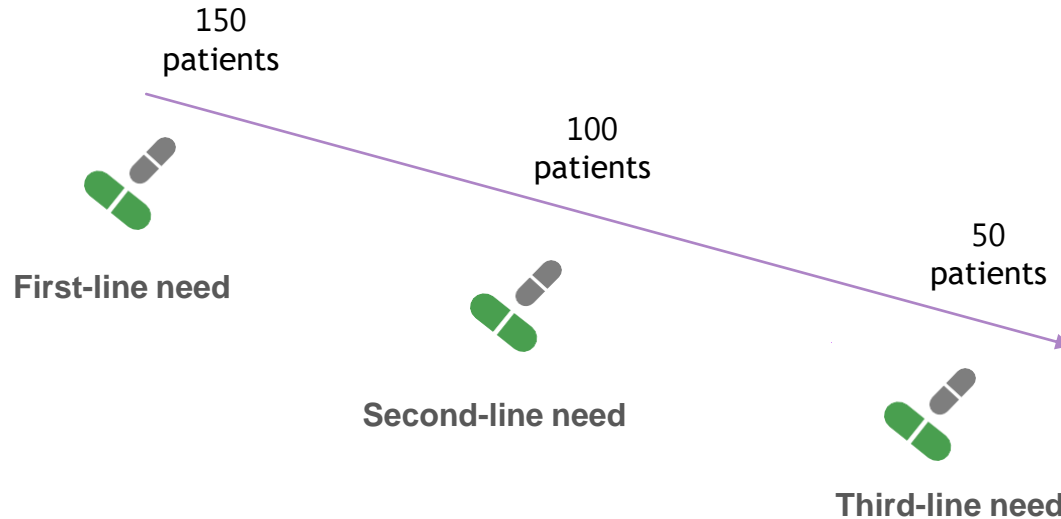
INC Research Project Costs	Unit Type	Number of Units	Cost per Unit USD (\$)	Total Cost USD (\$)
Investigator Meeting Preparation/Attendance	Meeting	1	80,000.00\$	80,000.00\$
Project Oversight	Months	2.00	1,750.00\$	3,500.00\$
Recruitment and/or Retention Materials Development	Materials	15	1,000.00\$	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

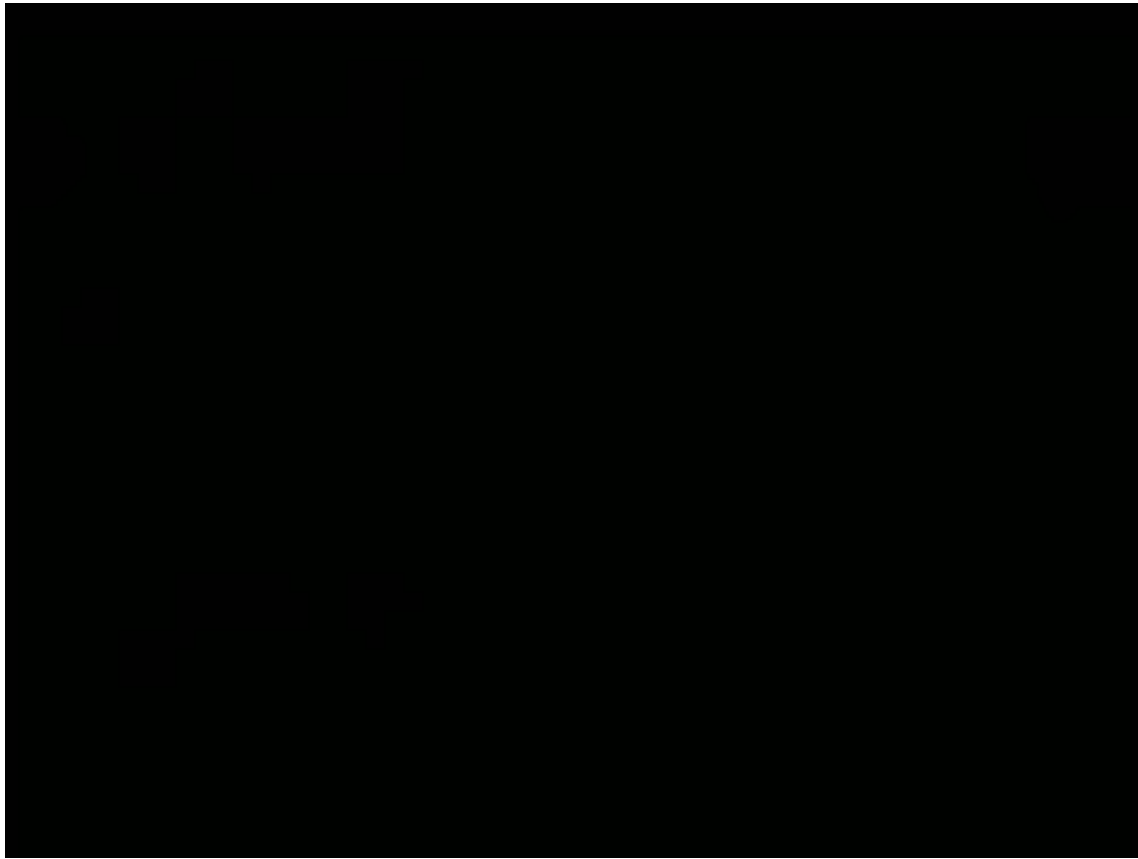


Missing Component



KIT items defensing







QA Budget

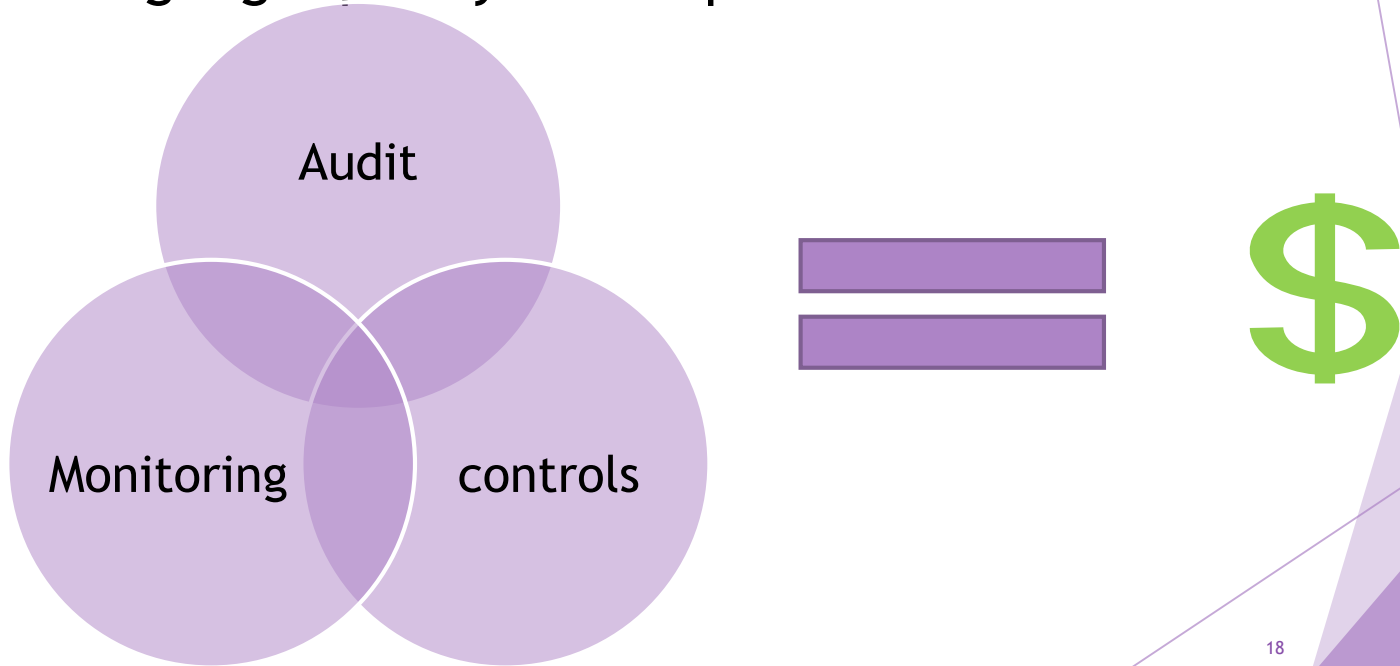
Quality assurance budget

trail integrity and quality is the main objective



Quality assurance budget

Assuring high quality has its price

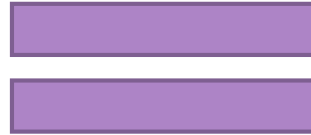


Quality assurance budget

Visits on site

Monitoring plan &
CRO
communication
plan

Audit plan by an
independent
quality consultant



Quality assurance budget

CT Center



Central Lab





Controls & Monitoring

Controls & monitoring

Payment Approval Process

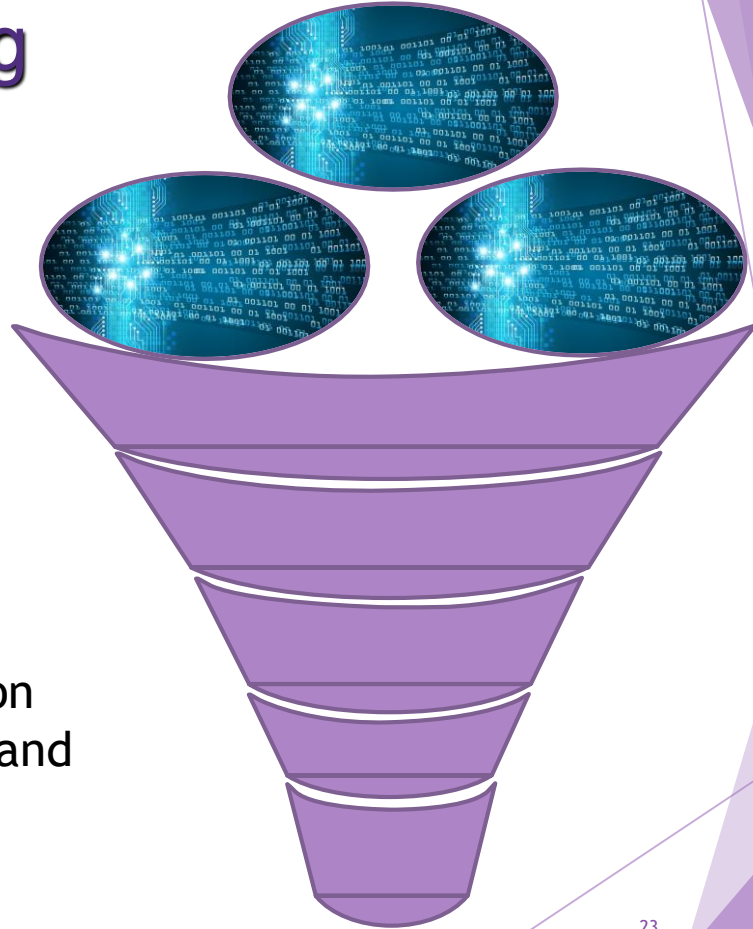


Controls & monitoring

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 | W www.grantthornton.co.il

