

David Eichenbaum, MD
Retina Vitreous Associates of Florida
Partner and Director of Research
Collaborative Associate Professor
University of South Florida College of Medicine
Tampa, Florida

Clinial Trials: How to be Profitable

1

Disclosures

S: Speaker, C: Consultant, I: Investigator, E: Equity/Stockholder, F: Founder (Role Over Calendar Years 2024-2025)

- dDMT I,C,E
- Alkermes C
- Amgen/Alcon I
- Allergan/I I
- Amaris C,E
- ANI/Alimera C
- Annexon I,C
- Apellis C,S
- Avellanis I,C,E
- Avicenna I
- Bausch & Lomb C
- Bayer I,C,S
- Boehringer-Ingelheim C
- Boston Image Reading Center E
- ColMens C
- Complement Therapeutics C
- CorSight/Westrum C
- Crinetics C
- EcoRx C
- EyeBio I
- EyePoint I,C,E
- Genentech I,C,S
- Gyroscope I
- Harrow C
- Ionis I
- Janssen I,E
- Kodiak I,C
- Kiyax C
- Janss Kzin I
- Mylan I
- Neurotech C
- Notal Vision C
- Ocular Therapeutics I,C
- Oculus C
- Ocushire C
- OccuTerra I
- Olin C,E
- Opthea I,C
- Orasis C
- DNLI
- Oculisak C
- Pliant I
- Recens Medical I,C
- Regeneron I,C,S
- Regenerix I,C
- Revue C,E
- RetinAI I,C
- Roche I,C
- Samsara C
- Stealth I,C
- Tlaxac C
- Unity I,C

2

The 3 Keys to Success

- Smile and Have a Good Attitude
- Say 'Yes'
- Go to Meetings

"Showing up is 80 percent of life."
– Woody Allen & Marshall Brickman,
New York Times August 1977

3

An Engaged MD Principal Investigator (PI) is Required for a Clinical Science Program to Succeed

4

Primary Goals with Early Trials

<p>1</p> <p>Enroll, Enroll, Enroll</p>	<p>2</p> <p>Understand and negotiate clinical trial budgets and agreements</p>	<p>3</p> <p>Monitor clinical trial collections</p> <ul style="list-style-type: none">• Consider a Clinical Trial Management System
--	--	--

5

You've Already Achieved That...
What's Next?

6

You Want to Start Making a Profit

7

Clinical Science is Transactional

8

P&L for your Clinical Trial Program

<u>Revenue Centers</u>	<u>Cost Centers</u>
• Subject Recruitment	• Doctors
• Subject Retention	• Staff
	• Rent
	• Equipment
	• Utilities
	• Opportunity for SOC
	• Opportunity for Drug Profit

9

Where do you have Leverage?

- Scale – increase recruitment, retention, throughput
- Staff – associate pay to performance
- Equipment – sponsor assistance
- Budget – increase payment per subject

10

Increase Recruitment

- Your **Clinic** is your source of business
 - Get your Doctors engaged
 - Get your Clinical Trial staff engaged
 - Get your Clinic Staff engaged
 - Get your Referral Community engaged

11

Increase Retention

- Emphasize the **high quality care** in trials
- **Add value** to recruit and **retain** subjects
 - Provide a positive clinical experience
 - Provide snacks and drinks
 - Negotiate transportation
 - Negotiate stipend
- **Praise** your subjects
 - Emphasize humanitarian nature of clinical science
 - Emphasize providing for the next generation

12

Increase Throughput

13

Scaling Your Clinical Trial Program

- Redundancy
- Reward
- Reinvest
- Ramping-Up Efficiency
- Remain Vigilant

14

Redundancy

- Clinical Science is the **most efficient** line of business
- Downtime is expensive: **Zero** Downtime
- MD, Coordination, & Clinical Staff Redundancy Reduces Downtime
 - Recognize and retain your best talent
 - Cross-train your staff
 - Hire when you must

15

Reward

- People respond to incentive
- Incentives must be appropriate and proportionate to role
- MD incentive is **most important**
- CSC incentive is **close second**
- Ask your staff "Do you feel appreciated?"
- Put in the time to team-build

16

Reinvest

- Clinical Trial CAPEX may be different from practice CAPEX
- Should be separated and paid by clinical trial revenue
- Engaged MD-PI listens to CSC's, sponsors, monitors **in that order**
- Not **all** scientific CAPEX produces more clinical trial revenue
 - Some makes clinical trials easier for CSC's
 - Some makes site more appealing to sponsors
 - Some makes more revenue

17

Ramping-Up Efficiency

- Ongoing process
- Most efficient to run clinical trials in parallel with clinic
- Requires **staffing and space**

18

Remain Vigilant

- The Engaged PI needs to be situationally aware
- The Research Management and Practice Administrator need to be situationally aware
- The CSC's need to be situationally aware
- **Meet regularly with the PI present** to ensure CSC and staffing needs are addressed

19



Active Clinical Study Marketing

Incentivize MD's to Recruit

Keep Potential Subject Lists for Upcoming Trials

Re-Examine Clinical Operations

Actionable Growth Strategies that you can Start Today

20

Study Marketing

- Markets both the clinical trial program **and** the practice
 - Referring MD's/OD's often do not recognize the difference
 - Make study referrals **easy**
- Funded by the **sponsor** of the clinical trial
 - Initial budget or budget amendment
- Many options
 - Referral dinners – improve attendance with CE credit when permitted
 - Internal and Community Newsletters

21

Incentivizing MD's to Recruit

- **Financial incentive** will drive recruitment and participation
 - Must be significant, tangible, and immediate
 - Must be compliant with anti-kickback
- Explain the **indirect** value of clinical science at MD meetings
 - Ability to care for uninsured/non-par patients
 - Reputation locally
 - Reputation nationally
 - Opportunity for further sponsor engagement

22

Keeping Potential Subject Lists

- Most Clinical Trials study **common** retinal diseases
- Coordinators should always **keep lists** of patients with common **chronic** diseases under study
 - Geographic Atrophy
 - Diabetic Macular Edema
 - Proliferative Diabetic Retinopathy
- Develop a Screening Plan once a disease state trial is active
- MD's and/or clinic staff can help with this – at **every** office

23

Re-Examining Clinical Operations

- Time – know how long clinical trial visits are
- Space – challenges are where to fit and when to expand
- Staff – use as much existing staff as possible, hire as you grow
- **Flexibility** – look for **what works** and **make changes**

24

Active Clinical Study Marketing

Incentivize MD's to Recruit

Keep Potential Subject Lists for Upcoming Trials

Re-Examine Clinical Operations

Actionable Growth Strategies that you can Start Today
