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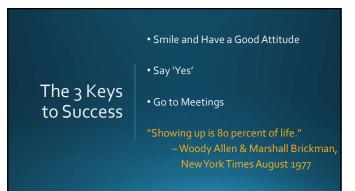
# Clinial Trials: How to be Profitable

#### Disclosures

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

<ul> <li>4DMT I,C,E</li> </ul>	<ul> <li>Boston Image Reading Center E</li> </ul>	<ul> <li>Kodiak I,C</li> </ul>	ONLI
AbbVie C			Outlook C
Aerie/Alcon I	<ul> <li>Complement Theapeutics C</li> </ul>		
Allegeneis	CorEvitas/Vestrum C	• Mylan I	<ul> <li>Recens Medical I,C</li> </ul>
			<ul> <li>Regeneron I,C,S</li> </ul>
ANI/Alimera C			Regenxbio I,C
Annexon I,C	• EyeBio	<ul> <li>Ocular Therapeutix I,C</li> </ul>	
Apellis C,S	<ul> <li>Eyepoint I,C,E</li> </ul>		RetinAl I,C
Astellas I,C,E			
Aviceda	Gyroscope I		
Bausch & Lomb C	Harrow C		
Baehringer-Ingelheim C	Jannsen I.E	Orasis C	

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

## Primary Goals with Early Trials



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

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# You Want to Start Making a Profit

Clinical Science is Transactional

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# P&L for your Clinical Trial Program

#### Revenue Centers

- Subject Recruitment
- Subject Retention
- Doctors Staff Rent
- Equipment

Cost Centers

- Utilities
- Opportunity for SOC
- Opportunity for Drug Profit

## Where do you have Leverage?

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

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#### 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

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#### **Increase Retention**

- Emphasize the high quality care in trials
- Add value to recruit and <u>retain</u> subjects
   Provide a positive clinical experience

  - Negotiate transportation
    Negotiate stipend
- Praise your subjects
  - Emphasize humanitarian nature of clinical science
     Emphasize providing for the next generation

# Increase Throughput

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# Scaling Your Clinical Trial Program

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

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## 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

#### Reward

- Incentives must be appropriate and proportionate to role
- CSC incentive is close second
- Ask your staff "Do you feel appreciated?"

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#### 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

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## Ramping-Up Efficiency

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

## **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

Actionable Growth

Strategies that you can Start Today

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Active Clinical Study Marketing

Incentivize MD's to Recruit

Keep Potential Subject Lists for Upcoming Trials

Re-Examine Clinical Operation

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## 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

#### 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

  - Reputation nationally
  - Opportunity for further sponsor engagement

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## **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

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#### **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

#### Active Clinical Study Marketing

Actionable Growth

Strategies that you can Start Today

Incentivize MD's to Recruit

Keep Potential Subject Lists for Upcoming Trials

**Re-Examine Clinical Operation** 

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