Clinical Trial Program Series

Program Overview: This program is a series of 3 panel discussions with industry and government partners, focused on providing high level insight into the clinical trial process. Each event will have its own specific focus, while contributing to a sequential flow for the series. Experts from varying backgrounds have been selected for each discussion to help provide a more robust and complete overview of key considerations and event topics for each discussion.

Goal: The goal of this program is to provide early-stage startups, stakeholders, and others, with expert insight and knowledge into the clinical trial process. From attending these discussions, attendees should have a better understanding of clinical trials, the necessary steps needed to develop a plan that will lead to successful study outcomes, insight into key considerations for the process and have a better understanding of what partners to engage with, and when.

Agenda:

12:00pm – 12:30pm: Opening Remarks
12:05pm – 12:10pm: Panelist Introductions
12:10pm – 1:10pm: Panel Discussion
1:10pm – 1:25pm: Q&A
1:25pm – 1:30pm: Closing Remarks

Webinar Instructions: These discussions will take place virtually via Zoom, a calendar invite containing the call information will be sent to each panelist. Panelist may join the event 30-minutes prior to the event start time to participate in a "meet and great" session, run through Zoom controls, or ask any questions prior to the event starting. Brennan Fournier from Massachusetts Medical Device Development Center will be handling the event logistics.

Deliverables: For each panelist, a headshot and brief bio sketch explaining your current role and any relevant expertise you have in regard to clinical trials will be needed for the event page and promotional material. Please send this information to Brennan_Fournier@uml.edu by April 30th, 2021.

Panel Discussion 1: Medical Product Development 101

Topics of Focus:

- Clinical Trial Basics
  - Understanding your product
    - Intended use, indication for use, the market you want to enter, patient population, end users and preclinical evidence
  - Designing Your Study
    - Developing a protocol, Investigational plan, developing a data management/statistical plan, logistics/external labs, insurance reimbursement
  - Regulatory Requirements
  - EC/IRB and Informed Consent
- Site selection
  - What to consider when selecting a site and how to generate the best results/data
- Medical Device vs. Therapeutic
  - Study considerations/How each differs
  - Clinical Study vs. Clinical Trial
- Developing an MVP and manufacturing a product for studies
- The importance of strategy and planning

Panelist Questions:

1. What are the basic logistical considerations that need to be addressed when thinking about conducting a clinical trial or study?
2. Who should you rely on for support in developing a protocol and when is the best time to engage?
3. Discuss the importance of understanding your product and its intended use/indications. Is there any type of preclinical evidence/animal studies you should have?
4. What criteria should be used when trying to select the appropriate site?
5. What needs to be thought about in terms of patient population for the study? What should you do if you're struggling with patient recruitment?
6. At what stage in the MVP development should you start to consider manufacturing a product for studies?
7. When we talk about medical devices vs. therapeutics, how does each study type needed differ?
8. What needs IRB approval and what does the IRB look for? Discuss how this related to Informed Consent.
9. How do I know if I need a clinical study or a clinical trial?
10. When designing your clinical study, what are the necessary steps to consider and the regulatory requirements?
11. Discuss developing an investigation plan/developing data and what should you do if the data you are receiving isn't going according to plan?
12. Please name the key takeaway you would like the audience to leave with

Date & Time: June 2nd, 2021 from 12:00pm – 1:30pm EST

Panelists:

- Barry Sands – President & Founder, RQMIS, Inc.
- Ann Han – Clinical Research Navigator, University of Massachusetts Medical School
- Melinda Hamer – Director of the Clinical Trials Center, Walter Reed Army Institute of Research
- Meg Johnson – Senior Manager of Clinical Research Compliance, University of Massachusetts Medical School
- Gustavo Cipolla – Associate Director of Preclinical, Ethicon, Inc
- Moderator: Eric Claude – Vice President of Product Development, MPR Associates, Inc.

Panel Discussion 2: Investor and Financial Strategy

Topics of Focus:

- Risk mitigation/de-risking strategy
- Reimbursement and legal considerations
- Budgeting - Cost expenditures
- Business planning and financial projections
- Best ways to raise capital and prepare for a large investment
- Big company/small company partnerships for funding studies
- Journey of medical device/therapeutic

Panelist Questions:

1. Are there any risks in-particular you should plan for and what are the best strategies that can be implemented to avoid these?
2. When seeking investors, how important is IP? What regulatory considerations should be explored prior to seeking investment?
3. What are the best ways you can save money during a study?
4. What should my expected costs be for a trial and/or study? How different is the cost for drugs vs. devices?
5. How important is having a business plan and should the financial projections for conducting a study be worked into it?
6. Are there any programs to take advantage of to help gain financial support for conducting a trial?
7. Discuss government funding of clinical trials and what someone should consider before approaching an agency
8. What is the best way to raise capital and how can I generate interest early on (i.e., proof of concept, etc.)?
9. What type of investors should I target given my stage of development (early, phase 1, phase 2, etc.)?
10. What is the most important thing an investor wants to see when approaching them for clinical trial funding?
11. Discuss the importance of budgeting your cost expenditures and how this impacts your likelihood of getting funding/investment.
12. Please name the key takeaway you would like the audience to leave with

Date & Time: June 9th, 2021 from 12:00pm – 1:30pm EST

Panelists:

- Nancy Briefs – President & CEO, AltrixBio Inc.; Entrepreneur in Residence, UMass M2D2
- Daniel Gottlieb – Associate Director, Broadview Ventures
- Bill Yelle – Entrepreneur in Residence, Partners Healthcare Innovation
- Vinit Nijhawan – Managing Director, MassVentures
- Anna O'Rourke – Senior Advisor and SME of Clinical Development, Biomedical Advanced Research and Development Authority
- Moderator: Nathaniel Hafer – Director of UMass Center for Clinical and Translational Science, UMass Medical

Panel Discussion 3: Key Considerations & Best Practices

Topics of Focus:

- Regulatory Strategy - Engaging with the FDA, Competent Authorities, etc.
- Trial speed and length
- The relationship between clinical trials and business plans
- Integrating clinical studies with your design control/development activities
- Engaging early on with potential partners
- Importance of developing a plan/strategy
- Sharing of best practices and advice
- Case studies/examples of well-run trials
- Conducting a trial during COVID-19
- Key opinion leaders
- CPT/Reimbursement strategy

Panelist Questions:

1. When should I engage with the FDA and what is the best way to do so?
2. How long should you expect a typical clinical trial to take? How does this timeline differ in a clinical study and how do you ensure quality results for a given timeline?
3. How important is it to engage with partners early on and who should you begin engaging with/when?
4. Discuss the importance of plan development and strategy, please share best practices and tips/advice
5. What does a well-run trial/study look like (relate to examples, is possible)?
6. As a result of the pandemic, how can we prepare to construct a virtual/decentralized trial? How can you prepare for this and still achieve the same goals and technology advancements?
7. How important is it to integrate your clinical studies with your design/development activities?
8. Share your thoughts on key opinion leaders and how this impacts the study
9. Discuss the importance of equity in trials
10. Discuss the journey a medical device and/or therapeutic should take to achieve successful study outcomes, and ultimately, a successful commercial launch from early-stage development and onward
11. When/who should consider CPT/reimbursement strategies and how does this have an impact on the financial considerations for the study?
12. Please name the key takeaway you would like the audience to leave with

Date & Time: June 15th, 2021 from 12:00pm – 1:30pm EST

Panelists:

- Bert Hartog – Senior Director, Janssen Clinical Innovation at Johnson & Johnson
- Stephen Tyrpak – Director, Clinical & Regulatory Affairs, of Garwood Medical
- Murray Sheldon – Associate Director of Technology and Innovation, FDA
- Kemi Olugemo – Executive Medical Director of Neurology Clinical Development, Ionis Pharmaceuticals, Inc.
- Hui-Hsing Wong – Senior Medical Advisor, Biomedical Advanced Research & Development Authority
- Moderator: Rachel Rath – Director of BARDA Alliance, Johnson & Johnson Innovation