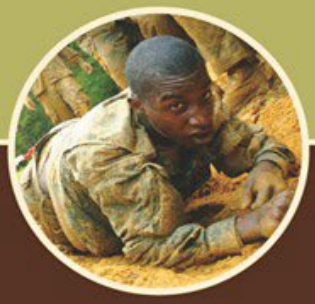
Drug Development Boot Camp

An Intensive Two Day Course
for Biotech, Pharma Executives,
and



Speid & Associates, Inc
SPEEDING NEW DRUGS TO MARKET®

Contents

Overview

Date

The 2024 Drug Development Boot Camp® will take place on 10 and 11 April 2024.

Time:

Day 1 6:30 am EST to 6:30 pm EST followed by Reception till 8 pm EST

Day 2: 6:30 am EST to 6:00 pm EST

Format: VIRTUAL only, in real time

Location: VIRTUAL

The Drug Development Boot Camp® has been held VIRTUALLY since 2020. Because of the impact of COVID19 on the costs of returning to the face-to-face format, the April 2024 intensive training will be held VIRTUALLY in 2024.

Why is the Drug Development Boot Camp® being held VIRTUALLY in 2024?

The Drug Development Boot Camp® will be held VIRTUALLY in 2024 for the following reasons:

1. The cost of running the Drug Development Boot Camp® face-to-face would require that the registration fees be doubled for the 2024 intake. The facilities that allow us to run the training at the level of excellence achieved for the past thirteen years, have increased their costs to make up for losses during the COVID19 crisis.
2. The facilities that we have evaluated have required that we provide various assurances regarding participants and their private medical status in relation to COVID19. Some of these stipulations require that all participants disclose their COVID19 injection status. Speid & Associates cannot and will not take on that responsibility, due to our understanding of medical privacy, informed consent, and risk benefit in relation to the use of medicines.
3. Some companies are still uncomfortable permitting attendance at face-to-face meetings.
4. We cannot obtain insurance regarding COVID19, in case there are public health reasons for not meeting face to face.
5. We have been presented with contracts by facilities (that can meet our required standard of excellence), that we could not possibly sign.

We have a lot of experience running the training VIRTUALLY. The training is exactly the same as is run face to face. Please do not miss out. Register for this training ***TODAY***.

Countries, Companies and Job Titles of Past Participants

Participants for previous Drug Development Boot Camp® have come from Australia, Belgium, Canada, Germany, India, Israel, Scotland, Sweden, Singapore, South Korea, Switzerland, The Netherlands, the United Kingdom, and the USA.

They have held all titles from CEO, CSO, CMO, and Senior Partner from top tier Venture Capital organizations, to Senior Scientist. If you are unsure if you qualify to take this training, please contact Dr. Lorna Speid.

Participants have come from 90% of the top 10 pharma companies, and many biotechnology companies. They have come from top universities, including Harvard University, Cornell University, and Brown University. They have come from the NIH/NCI.

Special Features for the 2024 Drug Development Boot Camp®

Special Features of the Drug Development Boot Camp® VIRTUAL

Division into Teams, Bravery and Courage

We will divide all Participants into two Teams to ensure all Participants feel supported as they undertake the training. The two Teams are called **Team Bravery**, and **Team Courage**. Participants will be able to network and form new relationships within their Teams, and also to work with others in their drug development Project Teams.

Piano Concert: Pianist - Dr. Josh wright.

Dr. Josh Wright, a professional concert pianist has treated the Drug Development Boot Camp® participants to moving piano recitals in 2020, 2021, and 2022. We have retained him again for 2024, for the Reception. His performance will be viewed via a virtual link-up. Family can view the recital from the same link if they are in the same room as the participant. Dr. Wright's bio is shown below:

Billboard #1 artist **Dr. Josh Wright** has delighted audiences across the United States and in Europe. The *Washington Post* described him as a pianist possessing "rarer gifts – touch, intelligence and the ability to surprise." *(link to article)* He performed his debut recitals at Carnegie Hall (Zankel Hall) and the Kennedy Center (Terrace Theater) in 2014. His self-titled album "Josh Wright" topped the Billboard Classical Traditional chart just three weeks after its release in April 2011. He also performed at Dolby Theater in Los Angeles as part of *America's Got Talent Season 9.* He was the recipient of the 2023 Stecher and Horowitz *Power of Innovation Award,* a national award given to an individual who displays innovation and entrepreneurship in the field of music. His work in the field of online music teaching and performance has reached over 175,000 subscribers and nearly 20 million views. Josh served on the piano faculty at the University of Utah

from 2016-2021.

Josh earned a Doctor of Musical Arts degree from the University of Michigan. He earned a Master of Music degree and a Bachelor of Music degree from the University of Utah. His principal teachers are Dr. Logan Skelton and Dr. Susan Duehlmeier. He has also studied privately with concert pianist, Sergei Babayan. Josh is married to Dr. Lindsey Wright, who earned her Doctor of Musical Arts degree from the University of Utah.

Josh was a prizewinner at the 2015 National Chopin Competition, and also won the Mazurka prize. He won third prize and the audience prize at the 2014 Washington International Piano Competition, first prize at the 2013 Heida Hermanns International Piano Competition, first prize at the 2013 Rosamond P. Haeberle Piano Award competition, the gold medal at the 2010 Seattle International Piano Competition, and first prize at the 2010 American Protége International Competition of Romantic Music. He was the second prize winner of the 2011 Music Teachers National Association National Competition. He was also a top prizewinner in the New York Piano Competition, the Louisiana International Piano Competition, and the Julia Crane International Piano Competition.

Josh has appeared numerous times with symphony orchestras including: the Utah Symphony, Temple Square Orchestra, Salt Lake Symphony, Timpanogos Symphony Orchestra, Great Falls Symphony Orchestra, Chopin Foundation Orchestra, Southwest Symphony, American West Symphony, SummerArts Orchestra, and the University of Utah Student Chamber Orchestra.

He has released seven albums, including *Sleigh Ride for Two* (2017) *Meditation* (2015), *My Favorite Things* (2013), *Josh Wright* (2011), *Gaspard* (2010), *The Complete Chopin Etudes* (2003), and *Josh Wright Debut* (2000).

In addition to performing, Josh is passionate about teaching. He has created numerous online video courses to help students of all ages and abilities improve their technique and musicality. Together with his wife, Dr. Lindsey Wright, and the AMAR Foundation, he authored an online beginner piano course for refugees in a camp located in northern Iraq, displaced from their homes due to war and terrorism. With the help of generous donors, over 200 digital pianos were delivered to these camps and two semesters of piano classes were taught to children wanting to learn music. Lindsey and Josh also founded the 2021 Susan H. Duehlmeier Piano Award, a project that awarded a talented young musician with a new Essex grand piano to further their piano studies and career.

Josh has appeared as a guest lecturer, adjudicator, and masterclass presenter at several festivals and colleges, including several presentations for chapters of Music Teachers National Association, the Spotlight International Piano Competition and Festival, Music Institute of Chicago, Bilkent Music Festival (Turkey), *Pianist Magazine* Online Masterclass Series (England), 5th Overseas Performers' Festival (Singapore), the 2021 Online Global Piano Summit, the 2021 Young Artist Piano Camp, Amalfi Coast Music Festival (Italy), University of Utah International Keyboard Institute (Salt Lake City, UT), Utah Valley University Piano Festival (Provo, UT), BYU-Idaho (Rexburg, ID), Snow College (Ephraim, UT), Castle Rock Music Camp (St. George, UT) and

Shoreline Community College (Seattle, WA). He has broadened his studio through online lessons where he teaches lessons to students on four different continents via Zoom and Skype

Josh is a listed Steinway Artist. He was inducted into the Steinway & Sons Teacher Hall of Fame in October 2019. He was also the piano double on the popular WB TV Series *Everwood.*

Special Guest: Colin Maclachlan, formerly of 22 SAS, Delta Force and Navy Seals

Colin Maclachlan, star of Channel Four's captivating reality TV drama *SAS: Who Dares Wins* and Channel 5's '*Secrets of the SAS'* is an operator with over 25 years of security and risk related experience.

Colin joined the army in 1989 and after 9 years in the Royal Scots passed selection first time aged 23 into 22 SAS. Colin was fortunate enough to have been involved in some of the more high profile and daring missions of the recent period. Only a handful of men have been involved in hostage negotiations, hostage rescue and been a hostage themselves and Colin is one of them. He waded through stinking swamps in Sierra Leone in West Africa to hunt down the West Side Boys, a

guerilla gang holding five British soldiers hostage. It was a mission so daring and dangerous they nicknamed it Operation Certain Death. The SAS recce teams secured the hostages' building and neutralised any West Side Boys prior to the main assault arriving and secured the prison building before the rest of the unit arrived wiping out the terrorists in 2000.

He was also the first sniper on the scene when a hijacked Afghan flight with 180 passengers landed in London in the same year, sparking a stand-off that lasted four days and was the longest standing hostage siege on UK soil to date. But four years later Colin found himself on the other side of a rescue mission after he was taken hostage in the Iraqi city of Basra. Blindfolded, battered and stripped naked, he felt a gun pressed to his head and heard them pull the trigger in what was a mock execution. Father-of-two Colin only survived long enough for British troops to rescue him because the terrorists who held him wanted to film his suffering in a propaganda video before they executed him.

Colin left the SAS shortly after doing an exchange programme with both Delta Force and Seal Team 6 and after doing security consultancy for the Saudi Royal Family, A-List Celebrities and US Media Networks decided to fund himself through university where he attained a First Class MA (Hons.) in History from Edinburgh University and an M.Litt in Terrorism from St. Andrews University. Colin is now involved in TV, Book, Radio and Video Games and also does a lot with charity being involved as Ambassador for the Lee Rigby Foundation, Pilgrim Bandits and NSPCC among others. He has also just founded his own charity *Who Dares Cares* that aims to link and support veterans as well as others that encounter stress.

Having had both an exciting and varied career, Colin is an excellent speaker on a wide variety of topics including Resilience, Teamwork, Leadership, Risk, Motivation, Conflict Resolution, Change Management, Negotiation and Performance. He is also an experienced presenter and host for events and is co-founder of Stoic Events.

Host: Speid & Associates, Inc.

Websites
www.speedingnewdrugstomarket.com
www.drugstomarket.com/drugbootcamp

Speid & Associates is a global and strategic regulatory affairs, and new medicine development consultancy. The consultancy has been in operation since 2004.

The company has expertise in global, international, EU and US regulatory affairs, and new medicine development. The firm provides global and strategic regulatory affairs and new medicine consulting services to large pharma, biotech, academia, government agencies, funders and any organization involved in addressing unmet medical needs. The company also conducts comprehensive due diligence for funders, VCs, and business development teams of pharma companies and biotech firms.

Expertise is available to address all types of therapeutics, including small and large molecules, gene therapy, combination products, diagnostic and therapeutic combinations, and cellular therapies. The firm has special practices in rare and neglected diseases.

The Drug Development Boot Camp® was started because many involved in new medicine development have a desire to take their skills to an advanced level. Organizations able to provide an advanced level of training in new medicine development are few and far between. At the Drug Development Boot Camp® the experts are trained on how to take their new medicine development skills to an advanced level.

Founder and Chair: Dr. Lorna Speid

Lorna Speid, B.Pharm.(Hons.)., M.R.Pharm.S., Ph.D., RAC, DTM
President, Speid & Associates, Inc.

Lorna Speid, B.Pharm.(Hons). M.R.Pharm.S., Ph.D., RAC is President of Speid & Associates, Inc. a global regulatory affairs and new medicine development consultancy. She works with small and large pharmaceutical companies, assisting them at all stages of the drug development process. She has experience working on US, European, international, and global strategic regulatory affairs. Dr. Speid has an excellent track record of success in regulatory affairs, and is considered an expert by her peers. She has experience with many therapeutic areas including oncology (solid tumors and hematological cancers), diabetes (Type 1 and Type 2), obesity, dermatology, transplantation, lupus, bone, women's health (hormone replacement therapy and osteoporosis), Sickle Cell Disease, and pulmonary diseases including asthma and COPD. Dr. Speid has worked with all therapeutic modalities, including small and large molecules, gene therapy, cellular therapies, combination products [drugs with devices], drugs with diagnostics, and devices. She has worked at all phases of the drug development process, including translational medicine, Phases 1 to 3 and post-marketing. She has secured marketing approvals in all regulatory and health authority jurisdictions.

Dr. Speid began her career as a Pharmacist in the UK, after which she worked as a Clinical Pharmacist in the hospital sector (London Teaching Hospitals). She then completed a Ph.D. at the Centre for Medicines Research International, into the Safety Assessment of Medicines, Pre and Post Marketing. The research that she conducted was used by the International Conference of Harmonization to amend the long-term toxicological requirements for new medicine development. These changes are still in operation today.

Dr. Speid has worked for large as well as small pharma companies, including Sanofi-Winthrop in the UK (now Sanofi), Ciba Geigy (HQ in Switzerland), and Novartis (HQ in Switzerland). Small companies that she has worked for include GeneMedicine/Valentis, Inc. (Director of Regulatory Affairs), NewBiotics (Vice President Regulatory Affairs and Project Management), and Avera, Inc. (Vice President of Regulatory Affairs). Dr. Speid was an officer at the last two companies. She has a Bachelor of Pharmacy degree with Honors from the University of London (Kings College), UK, and a Ph.D. from the University of Wales, College Cardiff, UK.

Dr. Speid is the author of *Clinical Trials: What Patients and Healthy Volunteers Need to Know,* which is published by Oxford University Press. The book is written for patients and healthy volunteers, and explains the process of clinical trials, equipping them to participate in clinical trials more effectively. The book is available globally.

Lorna is also the Founder and President of *Putting Rare Diseases Patients First!*®, a 501(c) (3) non-profit that educates patients with rare diseases about the drug development process so that they can effectively engage. This education is provided via Webinars, social media, and a Blog that seeks to provide information on topics of interest to patients with rare diseases.

Contact Dr. Speid by emailing LSPEID@SNDTM.COM or by telephoning her at +1- 858-793-1295.

Academic Collaborators

The Drug Development Boot Camp® has collaborated with Cornell University (1 year), Harvard University (8 years), and Brown University (3 years). Academic Collaborators receive partial scholarships for their participants to gain the benefit of this transformative training. If your university is at the forefront of drug research and discovery, collaborates with large pharma, and would like to access partial scholarships under a competitive process, please email Dr. Lorna Speid at email LSPEID@SNDTM.COM.

The Scholarship process will be in operation for the 2025 Drug Development Boot Camp®.

Some Comments

Drug Development Boot Camp® = Intensive training in new medicine development.

> "They train you to do certain things, and then you have to do them extremely tired." An SAS Officer

The Drug Development Boot Camp® is intensive! It accomplishes in two days what some courses cannot achieve in two years.

> "Come prepared to work hard. If you want to sit back, check emails, and drop in and out of lectures for two days, Drug Development Boot Camp® is not for you."-- Dr. Lorna speid, Founder and Chair of the Drug Development Boot Camp®.

Overview

The process of drug development is becoming more and more complex. At the same time, it is becoming more and more expensive. Only 11% of drugs will make it through the drug development and registration processes, to commercialization. Those involved with the process of developing new therapeutics (drugs, devices, combination products and diagnostics) must understand the process and be able to navigate it with great skill. Failure is incredibly expensive. Unfortunately, drug development skills are difficult to acquire, especially to an advanced level.

The Drug Development Boot Camp® uses accelerated learning approaches to simulate the drug development process so that hands-on experience can be gained. A mixture of large pharma, small pharma and expert Faculty members will ensure panel discussions are relevant, responsive and applicable to everyday situations that participants face. This program will consider the process from drug discovery (designation of a development lead) to global registration. The major aspects of development will be considered in a unique, systematic and coordinated way.

Your Questions Answered

How much experience will I need to take this training?

A good level of understanding of the drug development process is presumed. A minimum of 5 years of relevant experience is needed. In addition, all registered participants will be expected to complete reading assignments before the Boot Camp. To help you to get up to speed, and to ensure that you have a very productive two days at Boot Camp, you will be guided through a Pre-Boot Camp preparation process. This involves reading two books. You will also be given access to a special server which has carefully prepared reading materials and slide presentations, some with videos.

Who Should Attend?

- Researchers and drug developers from Pharma, Large Biotech, NIH, NCI
- Reviewers from Health Authorities
- Decision makers, CEOs, CFOs, COOs of biotech companies
- Researchers and executives involved with the drug development process
- Small and virtual company executives, scientists, and professionals involved with drug discovery and drug development
- Large pharma professionals involved with drug development
- Regulatory affairs professionals, clinical research professionals, senior research scientists
- Toxicologists
- Clinical investigators who would like to gain an understanding of drug development, or improve their understanding of the drug development process
- Senior scientists wishing to transition into drug development
- Physician investigators, Pharmaceutical Physicians
- Decision makers or financiers of the drug development process, Analysts, etc.
- Developers of digital tools, and tools involved with artificial intelligence – we particularly want to train such individuals and team

Register now: www.drugstomarket.com/drugbootcamp/

Should my company be represented?

- Does your company have employees or C-Level executives who have recently left academia?
- Do you work for large pharma or biotech?
- Are you an executive with many years of experience developing new drugs?
- Does your project team face questions that it cannot answer?
- Does your Team have knowledge gaps in the drug development area?
- Do you wonder why your company is experiencing challenges getting your company's drugs partnered and/or registered?

If you answered yes to any of the above, the answer is Yes – you **should** be represented!!

Register now: www.drugstomarket.com/drugbootcamp/

What benefits can I expect from participating in the Boot Camp?

- You will learn about drug development in a hands-on manner
- You will learn how to move drugs through the process of drug development
- You will hear from large pharma and successful small and mid-size companies about the lessons that they have learned in developing their drugs
- You will leave with knowledge and experience that you can apply to your company's drug development challenges.
- From interacting with large pharma experts, you will gain invaluable insights into what you need to do to make your program attractive to them for exit purposes
- There will be many opportunities for networking and working through challenges with peers

Register now: www.drugstomarket.com/drugbootcamp/

Some Risks of Not Taking this Training

There are many risks of not receiving this specialized training, especially for those in senior executive positions. We have listed some of them below. This list is **not** exhaustive.

- Wasting huge sums of investors' money on patent prosecution which will ultimately be useless, lead to costly litigation and prevent the asset from finding an appropriate exit.
- Spend many years and huge sums of money developing a drug or drugs that the market does not want, and will not pay for.
- Make costly mistakes throughout the development process, which will ultimately cost the company, one's reputation and may even lead to safety problems in those administered the company' products.
- Experience a lack of direction from the top management team because of a failure to take the time to receive real training in drug development.
- Clinical hold situations which are extremely costly.
- Failure to design a clinical program/clinical programs which could lead to registration of the drug.
- A US-centric approach, rather than a global approach to drug development. This will lead to many problems later in development.
- End up with a "good drug bad development syndrome".
- Face expensive CRO and consulting bills, with no additional assurance of success.
- You will be forced to rely on the input of CROs. There is a likelihood that you will be assigned the E Team by the CRO because of your inability to tell the difference between an A Team and an E Team.
- Inability to take the drug to the market in the timeframe promised to investors, analysts, the Board of Directors and patient groups.
- Inability to manage the expectations of the Board of Directors.
- Ineffective decision-making mechanisms.
- Inability to raise funds or to find an appropriate exit.
- Inability to work effectively with major health authorities.
- Loss of company, job and reputation.
- Failure to advance in your career due to surface level understanding of drug development

…. and many other risks, and challenges not listed here.

Pre-Boot Camp Preparation Process

All registrants for the Drug Development Boot Camp® will be enrolled in a proprietary Pre-Boot Camp preparation process. The reason that this process is so important is because we recognize that participants come from different backgrounds and will be bringing different types of expertise to the training. Completion of the Pre-Boot Camp Preparation Process ensures that all Participants will be on a similar level when they take the intensive two-day training. We recommend early registration to commence the Pre-Boot Camp process. You will find it will help you in your day-to-day work, even before you attend the intensive two-day training.

Register now: www.drugstomarket.com/drugbootcamp/

Costs for the 10-11 April 2024 Intake

The following costs are for the VIRTUAL meeting in real time. All payments are non-refundable. Please see the website for additional information regarding payments.

Cost is per Participant:

$5,500 if paid before 10/16/2023

Discounts for Bulk Registrations

Many teams have been trained at the Drug Development Boot Camp®. They have come from Pharma, Biotech, Academia and NIH/NCI. The typical size is ten registrations, for which two free spots will be provided. For smaller companies, one free place will be provided for five registrations, allowing six participants to be trained for the price of five.

Training Departments, HR Departments, and Chiefs of Staffs can enquire by emailing Dr. Speid at Lspeid@sndtm.com.

Overview of the Agenda

A detailed Agenda will only be made available to Participants on the first day of participation.

Day 1 ***Start at 7:00 am EST*** ***Participants - Breakfast from 6:30 am***	**Day 2** ***Start at 7:00 am EST*** ***Participants - Breakfast from 6:30 am***	**Special Features**
COMMERCIAL SESSION Drug Discovery to Product Candidate The criteria for selecting the lead candidate will be explored. A special case study on a futuristic pandemic and commercialization will be conducted.	CHEMISTRY MANUFACTURING CONTROLS (CMC) The inter-relationship of CMC to safety and efficacy will be explored in a lot of detail. The CMC session will also cover Process analytical technologies (PAT) and manufacturing scale-up.	This two-day intensive Boot Camp will be interspersed with workshops, breakout sessions, case study analyses and puzzles. The hands-on approach will enable those with experience in drug development to gain an understanding of areas that they are as yet unfamiliar with. Those with 5 to 30 years of experience will deepen their knowledge of the drug development process and will be able to apply their knowledge to complex drug development situations in carefully constructed Workshops. Anyone who has become very specialized (many drug development experts have), will leave with an important and insightful appreciation of other functions within the drug development process. The Drug Development Boot Camp® is extremely interactive. It is taught by expert drug developers. The Faculty are experts in their fields. The course content has been put together very carefully to achieve the goals of teaching about the Drug Development process in a lot of detail. Because of the workshops and case studies that you will work on, the learning process is fun and hands-on, but intensive. Information is imparted by the Faculty, but the understanding of this material is reinforced and tested throughout the Boot Camp as participants interact together. Participants are able to work on the material provided with other participants using case studies.
REGULATORY AFFAIRS The Target Product Profile and Development of the Regulatory Strategy The critical importance of the Target Product Profile and the process for defining it will be presented. The interfaces of marketing, clinical and reimbursement will be explored. The importance of developing a global regulatory strategy will be considered. A method for developing the global regulatory strategy will be presented.	The CLINICAL PHASE The four phases of clinical development, the goals of each, and the potential issues to be managed will be identified and explored in detail. Clinical strategy will be covered in a lot of detail. Clinical strategy will be covered in a lot of detail, including practical exercises on selecting the most appropriate clinical trial design. We will conduct a very detailed exercise on adaptive clinical trial designs, using specially designed software.	
PRECLINICAL DEVELOPMENT Preclinical Efficacy Different methods for demonstrating proof of concept during the preclinical phase will be presented and considered in detail. Scale up of the data obtained to preclinical toxicology studies will be considered. An interactive workshop will allow participants to work on real life preclinical situations.	WORKSHOPS - AFTERNOON OF DAY 2 Participants will be divided into project teams according to their levels of previous drug development experience, skills, and their objectives stated on a questionnaire. The Project Teams will work on drug development case studies. Each project team will report back to the whole group regarding how their case studies. The Faculty will present the responses. This is a time to consolidate all that has been learnt during the Boot Camp.	

Day 1 *Start at 7:00 am EST* *Breakfast from 6:30 am*	Day 2 *Start at 7:00 am EST* *Breakfast from 6:30 am*	Special Features
PRECLINICAL TOXICOLOGY Clinical Development and the inter-relationship with toxicological evaluation up to registration The interface of GLP toxicology studies, CMC and clinical will be considered in detail.	THE INDUSTRY – WHERE IT HAS BEEN, AND WHERE IT IS GOING Consideration will be given to how those who have completed the Drug Development Boot Camp® can make a strategic contribution.	Certificates of Attendance for continuing education purposes will be provided to all who finish the complete two-day intensive training. Day 1 will finish at 6:30 pm EST, and will be followed by a Reception. Day 2 will end at about 6:00 pm EST. The coveted Certificates of Completion can only be provided to those who remain to the end of the Boot Camp, without skipping out for meetings and teleconferences. We regret that exceptions cannot be made, for any reason.
Reception and Networking - optional This is a time to relax after a day of intensive learning. Network with your colleagues, make new connections and exchange experiences that were learnt during Day 1. Background reading will be provided for overnight reading, in preparation for Day 2.	PANEL Q&A AND DISCUSSION Your opportunity to ask remaining questions, discuss your individual project challenges, etc. Experts will take questions from the participants. These questions may be questions arising from the course or questions from their own drug development situations. Grand Finale – **Sending Out the Special Forces®** is a special time when all Special Forces trainees are commissioned to go out and solve the difficult challenges faced by patients. Mr. Colin Maclachlan, formerly of 22 SAS, Navy Seals and Delta Force, will address the participants.	

Some Participant Feedback from the

Drug Development Boot Camp® VIRTUAL 2022

It is always gratifying to receive positive feedback from the Participants. The feedback can be immediate, but also longer term, as Participants begin to practice what they have learnt. Here is some of the immediate feedback.

Hello Dr. Speid,

Thank you so much for sharing your knowledge and expertise in the Drug Development Bootcamp. It was the most challenging yet rewarding experience I've participated in.

Attached is the reporting back document.

Thanks again and take care

Hello,

Thanks for the great bootcamp. It was extremely informational and helpful.

Attached is the feedback form and reporting back form.

Thanks again,

Hi Dr. Teng, it was wonderful to hear form you during the Drug Development Boot Camp®. I am going to be taking the learnings from your session on adaptive clinical trial design with me, as I work forward. Many thanks again!

Some Participant Feedback from the

Drug Development Boot Camp® VIRTUAL 2021

Participant Feedback from the second Drug Development Boot Camp® VIRTUAL
The feedback from the second Drug Development Boot Camp® VIRTUAL (twelfth Drug Development Boot Camp®) held on 17-18 November is included below. The experience was wonderful. Everything went very smoothly. The completion rate was 92%.

Thank you again for the bootcamp! Everything was very well planned, and I learned a lot. I would recommend it to a colleague or friend, and even take it again, should the opportunity present itself!

Dear Dr. Lorna Speid,
Please see my participant response form. Thank you so much to you and your team for putting this program together. This was so valuable for my understanding and career. Even though I had to drink 3 shots of coffee for two days to make it through, I am so glad I was able to actively participate and really learn from the speakers. Also, I really appreciate you making this fun with the wonderful piano recital and the "Team Courage" and "Team Bravery" videos. You were so professional throughout (and on the West Coast too)! I am glad I was exposed to the whole process of drug development early on in my career so it can activate my thinking and actually have the context to understand what different functional groups like CMC and Toxicology are saying as it pertains to work.

Thank you for the great boot camp.

Participant Feedback

Drug Development Boot Camp® VIRTUAL 2020

Participant Feedback from the very first Drug Development Boot Camp® VIRTUAL

The feedback from the very first Drug Development Boot Camp® VIRTUAL held on 18-19 November is included below. The experience was truly remarkable for the commitment shown by all Participants to complete the training VIRTUALLY. A 100% completion rate was achieved.

"Dear Lorna

Here is my participant survey. This Workshop was super informative. Thank you!"

"Good morning Lorna –

Please see attached feedback and reporting back forms. Thank you again for a fantastic boot camp."

"The thorough and robust content makes this course. I am excited to apply the learning to my day-to-day activity. Excellent job overcoming the virtual challenge."

"An excellent, comprehensive program diving deep into the drug development process with engaging discussion leaders and real-world application workshops. I highly recommend this training for the pharmaceutical professional looking to develop a holistic understanding of drug development."

"Dr. Speid and Lorraine and Team thank you so much for the intense training – wealth of information.

I really appreciated all of your hard work to put this event on in a virtual manner!

Have a great holiday season!"

"Comments/ Feedback: be prepared for a lot of reading and watching videos as this is indeed intense. I think your team did a great job with preparations and it's astounding the amount of work your team accomplished to make this training so great. I learned so so much! I have a great appreciation for all the work our company does to get more medicines to patients!!!!!!!!!!!!!!"

"The faculty you have involved in the training are unbelievably smart and great teachers. Such patient people as well. They really are experts in drug development. They make this training well worthwhile."

"Dear Dr. Speid:

Thank you so much for conducting such an informative training program. Though it was very intensive program, I am really glad that I have undertaken the Drug Development Boot Camp as it helped me learn a lot about the complex drug development processes and understand the intricacies of decision making processes. It was really very interesting working with individuals of diverse background and the faculty was simply amazing. You really have done a good job in bringing in the diverse team together and creating an environment that promoted supportive learning. I would also like to extend my sincere thanks to Lorraine, Anna and all faculty members. I have attached the PDF file containing, the participant survey, reporting back form and comments form."

"Dear Lorna,

Thank you kindly for the update. I have attached my Reporting Back, Survey, and Quote Me forms to this email. A huge thanks to you and the faculty for such a successful and educational virtual boot camp!"

"I believe the Drug Development faculty handled the virtual format with great skill! The zoom breakout rooms were very successful, and I enjoyed the various faculty who popped in from time to time to give advice. For a virtual environment, the whole event felt very connected. This has been a demanding and highly rewarding course. I would highly recommend the Drug Development Boot Camp to anyone who is up to the challenge and interested in expanding their knowledge in everything drug development."

"The Virtual Drug Development Boot Camp® was an intensive training that I have undergone in a virtual platform. The Workshop sessions were beneficial and Faculty members joining to give context to the assignments was helpful. I learned a lot about the drug development process in the context of the life threatening and non-life-threatening drug development. The acceleration presentations by the faculty members before each session was informative in concisely outlining each session. Really appreciate the time and efforts that each Faculty member and staff took in formulating such as concise, well rounded intensive boot camp in the virtual platform. It was fascinating to see the thought processes of my classmates (in the assigned company and group) during the workshop sessions. Throughout the camp. The

environment was very supportive and promoted learning. I will surely. Recommend this boot camp training program to my colleagues and peers. It was unfortunate that each of us was not able to have a networking opportunity with broader team members who attended the virtual boot camp.

Thank you again for allowing me to attend the course. It was tremendously helpful. Please see attached survey. I would highly recommend this course to anyone planning to move into management level and higher in the pharmaceutical industry. This is very helpful in ways to understand how all the different functions impact each other, and how to better strategize. I think this training should be a requirement for anyone going into CMC."

Participant Feedback from Previous

Drug Development Boot Camp®s held Face-to-Face

Feedback on the Overall Boot Camp Experience – Face to Face

"Please Quote Me!"

"A very good overview of drug development A to Z."

"A comprehensive learning experience in drug development. Terrific experience!"

"I think this intensive course should be taken by any academic considering a drug development start-up. There is much to think about and properly plan ahead for drug development to approval."

"Intensive Drug Development Boot Camp that everyone who is interested in building a career in drug development should take. Complete life cycle management from Discovery to Commercialization."

"The mock projects are extremely helpful, and help with Teamwork."

"This was a very helpful overview of the drug development process."

"Great immersive learning experience."

"Well organized materials and sessions. The Boot Camp has equipped me with new knowledge. I'll never approach / see drug development the same again!"

"Excellent overview of later stages of drug development. Great workshops, informative and thought provoking."

"Overall excellent course."

"This Boot Camp enhanced my knowledge in the drug development aspects and will help me to better function as a program officer for translational sciences portfolio at NIH."

"Comprehensive training towards a drug development Blackbelt!"

"DDBC is built for a diverse audience. I found tremendous value in the camp, even a member of the animal health pharmaceutical industry."

"Congratulations on completing 10 years of Drug Development Boot Camp®! Great sessions!"

"Very enjoyable few days with valuable workshop break-out sessions and very experienced speakers …. Maybe Day 1 was too much and would love more time on PKPD and toxicology and trial design."

"It is a well organized course, which provides a lot of useful information for drug development."

"Fantastic overview of the interconnected pieces of drug development. Would certainly recommend to my colleagues and anyone involved in advancing novel therapeutics into patient."

"Great all-around intro to overall drug development. Good for anyone in the industry."

"Very comprehensive overview of different aspects of drug development."

"The most comprehensive Drug Development course! Two days of great learning, collaborating to solve problems, and getting the Big Picture of Drug Development! I would do it again!"

"I wish I had taken this class on Day 1 in pharma."

"Very well-organized learning experience." "Speakers fantastic, even on somewhat dry subjects."

"Diverse and very nice attendees."

"Excellent coverage of the many areas relevant to drug development."

"I work in R&D (disease modeling, phenotype discovery and early drug discovery) and this Boot Camp was a great and productive way to learn about all the downstream processes and challenges in drug development pipeline."

"I wish I had this training years ago - it was very insightful into all drug development areas, including preclinical and CMC."

"Case studies were really useful." "Food and location were great."

"This gave me a very comprehensive understanding of drug development process with all elements from GLP tox to clinical trials to commercialization."

"Loved the setup. Lectures and network opportunities. Thank you."

"Content was great, presenters were WONDERFUL, cases were very engaging."

"An intense but informative 2-day session. Engaging speakers and team activities made for a great learning experience."

"Speakers/presenters were fantastic!"

"Breakout workshops were the most valuable aspects of the Boot Camp."

"Meticulously planned and executed."

"High quality speakers. Very well laid out learning materials."

"The workshops are excellent in getting to know other attendees, their expertise, and different ways of looking at our industry, and how to do things better."

"A very informative course that provides all elements of drug development with good tools for future reference during the day to day activities."

"Excellent program. Highly recommended." "Excellent program. Highly recommended."

"It takes a Team to create value. Well you have a great Team and this course definitely added a lot of value to me. Thank you."

"The Boot Camp provides a great opportunity to see drug development end-2-end, understand how different components play together, and define better ways to achieve the challenging mission to bring a new medicine to patients."

"Thorough and digestible approach to learning the key aspects of drug development."

"An excellent overview of drug development."

"The best overview of a complex industry I've ever been exposed to. Helps to streamline the Thinking process and defines the frame for overall development strategy. Thank you, Lorna and the Faculty!"

"The case studies are very interesting and informative."

"Worth every minute. By far the best overview of Drug Development I've seen."

"Great course for people new to pharma, biotech. Good refresher for others.

Workshops are most valuable."

"Wonderful materials. Will keep for constant reference."

"Well hosted, well run, and lots of enjoyable work. Amazing facility. Thank you."

"Definitely recommend to others. Very educational for commercial, CMC and clinical design."

"Thank you for including adaptive design. It was important to me, and will be done."

"Very informative Tufts data presentation about industry snapshot. "

"Cost driver specifics were eye-opening and

helpful." "Consider building in the role of Quality

in the various puzzle

pieces. They touch on all processes and it was disappointing to be excluded."

"I enjoyed the Workshop groups and workshop sessions and think it may be worth decreasing the formal presentations and increasing the Workshops further."

"I registered for the Boot Camp with quite some doubts about how much we could learn from a short two day period. It turned out the camp was very well organized; with pre-reading, lectures by industry experts, and hands-on practice for each of the major aspects of drug development.

"I had a great experience from learning from the panel members and the attendees through plenty of discussions."

"A thorough overview of the drug development process. Great opportunities to share experiences with peers in the workshops."

"A great way to see a lot in a very condensed format." "Loved the venue!"

"I would definitely recommend this program to my colleagues who are passionate about drug development."

"I found the workshops to be very useful and will be recommending it to my colleagues."

"I wish I had taken this course 10 years ago. It filled in a lot of gaps in my understanding of drug development."

"It was a great overview of the different disciplines and the right amount of time was spent on each piece."

"Very well organized Workshop; learned a lot in short time. Very good quality of participants."

"Good overview of entire drug development processes with the latest technologies. Case study and group workshop are efficient format."

"Great program with broad topic coverage. Case studies and workshops were very useful."

"Excellent Faculty, superbly organized. Subject lectures followed by workshops drove home concepts."

"Overall, great presentation."

"Very good design and well managed! Speakers were wonderful."

"Developing preclinical and CMC strategy was very informative. Workshops are the key element of going over what was learnt in each session."

"Great sessions and reading materials. Schedule is intense but results are apparent."

"It was a decent overview of the material."

"Overall great overview and gives a better understanding of the other aspects of drug development that are related to my day to day work."

"I really enjoyed learning about the whole pharmaceutical process from start to end. As I am embedded in early discovery in my day to day job, this was a good way to understand the later stages.

The Workshops were fantastic for applying what we were learning and to even learn from others in our Workshop groups who may have been in that area."

"I greatly appreciate the time and expertise shared by the speakers. Really enjoyed the breakout session with the various groups on different scenarios. It is invaluable to directly interact with peers for problem solving."

"I like that participants were each required to report back.".

*"Workshops were *FANTASTIC*"*

"Engaging speakers. Thank you!" "Very informative training!"

"Intense --- in the best way possible. All subjects were covered thoroughly at a level that could be understood. Thank you for the background reading!"

"I was quite worried that I might not have enough background knowledge to get much out of the course. However, the pre- readings helped boost my knowledge in areas I was familiar with, while introducing the basics for those I was not well-versed in.

The spirit of learning together that the other participant brought was also helpful in forming a collaborative environment, especially for the Workshops."

"Comprehensive review of all functions and integration required for development."

"Comprehensive modules covering key aspects of drug development. I found it very useful to study these topics and get new insight; Also met new colleagues from various organizations."

"Tremendous! I love the case study methodology." "In

depth coverage of multiple areas." "Workshops"

"Faculty/support excellent!"

"Very efficient crash course to cover an enormous knowledge space. This will change how I think about my research program."

"Great people here of very diverse expertise backgrounds, and this was great to experience."

"Workshop 2 was very good."

"People (including me) really enjoyed Dr. Chang's talk and thought that getting feedback on the examples beneficial. Very few speakers gave direct feedback."

"Brilliant organization and highly professional set-up."

Feedback on the Commercial Session

"Case study was very good exercise." "This was an excellent session."

"Very balanced overview to connect the end to end overview of drug development.""

"Excellent session."

"Great session. Importance of considerating all the different stakeholders and criteria for making a commercial decision to move forward."

"Tony Sarraino is a great presenter" "Enjoyed case."

"Understanding payers influence my customers' decisions and the EEF concept for prioritization - my partners are performing that now to justify next year's budget."

"Greater understanding of the complexity associates with drug discovery activity."

"Liked Workshops very much."

"I have many questions to take home to my company."

"Enjoyed the case study - vaccine market is not one I'm familiar with so good learnings."

"Great session."

"Good engaging speakers - the difficulty of reimbursement was well covered."

"Considerations regarding market access and commercial value should be considered from the beginning of the development program, and not just during clinical development. It's not just about regulatory approval."

"Great session."

"Interesting new insights into business strategies."

"Increasing benefit of molecular biomarker to predict perspective."

"Good insight on how to select leads, and importance of studying metabolites."

"Now I understand the marketing and reimbursement perspective of drug development. Very useful."

"The need to understand target product profile and the druggability and consideration and not just efficacy and toxicity."

"Well laid out."

"Commercial decisions are based on very detailed financial calculations (ROI). This seems like it should be obvious, but on the discovery we don't often get to see the math behind the decisions reflected in our companies' press releases."

Feedback on the Global and Strategic Regulatory Affairs Session

"Interesting insights into Priority Review Voucher."

"Very informative to delineate the differences between the IND/ CTA."

Very important to understand the 7 Mistakes. Helpful to be told this."

"I will Keep the 7 most common mistakes listed on my mind throughout the programme development."

"Carlos was great."

"Keep the 7 most common mistakes listed on my mind throughout the programme development."

"I liked the idea of a strong plot for development of CTD/ regulatory strategy."

"Be the expert on your drug."

I learned about the difference between plan and strategy."

"Importance of creating a regulatory strategy early with review often."

"7 Mistakes to avoid for IND/.CTA - failure to develop a TPP etc."

"As this impacts many other development disciplines as well, one could put more emphasis on this topic."

"7 Mistakes in Regulatory Affairs."

"Things I haven't even considered before - good perspectives."

"Learnt how important it is to have a comprehensive regulatory strategy."

"Plan your TPP so you can determine key Go/No Go details early. Don't rush talk with FDA. Open a dialogue."

"7 Mistakes was a nice reminder. Don't let questions become justifications."

"The 7 Mistakes. Will print this out and keep on my desk."

"Importance of the Target Product Profile."

"Importance of TPP." "Very informative session."

"To design proper studies that will define the TPP."

"This session gave a thorough understanding on the IND/CTA application and about registration of drugs."

"Terminology relevant for various regulatory requirements (CTA, etc.)."

"Developing relationships with FDA."

Feedback on the Preclinical Efficacy Session

"Good overview of PK/PD essentials."

"Very interesting discussion on delayed effects."

"Information and content was clear even though the topic is foreign and distant for me."

"The mathematical modeling to determine dosing was very relevant. The exercise we were given was extremely useful."

"This was an excellent session. How PK relates to PD using the applied math software."

"The Workshop questions were great and really reinforced the learnings."

"Mathematical modeling is fun."

"I now understand PK/PD data and how to interpret the data." "The bath tub model is a great way to conceptualize PK model."

"Stronger appreciation for the importance of PK/PD relationship for clinical trial progression."

"Information and content was clear even though the topic is foreign and distant for me."

"The mathematical modeling to determine dosing was very relevant. The exercise we were given was extremely useful."

"This was an excellent session. How PK relates to PD using the applied math software."

"The Workshop questions were great and really reinforced the learnings."

"Mathematical modeling is fun."

"The bath tub model is a great way to conceptualize PK model."

"PK/PD models can help us make predictions about as yet unstudied scenarios."

"Much better understanding of PK/PD"

"Great introduction to PK/PD. Modeling helps."

"Modeling - is this something I can discuss with my sponsors? Yes! This will help me understand the evaluation they have gone through. Great presentation! Learnt a lot."

"Ability to understand the importance and utility of PK/PD data."

"The bathtub analogy for PK/PD is fantastic."

"Very interested in computerized model for planning.

Ability to model different dosage levels/schedules."

"Super helpful for me. Good charts for cross species."

"Interesting to see how physiology affects PK/PD."

Fast! But good overview of preclinical. Would like to hear more about preclinical R&D and tox and MABEL approach to FIH biologics."

"PK/PD modeling and the Workshop were very helpful and I really learned a lot."

"Really interesting modeling workshop. Good speakers."

"Very good"

"Use of the pharmacology software was a great way to apply the information offered during the lecture part."

"PK/PD software is great."

"PK/PD modeling is very very useful." "Enjoyed the session."

"So far I have only been thinking about primary PD. This session gave me thoughts on secondary PD.

using the software to model PK/PD was eye opening. I had seen similar graphs before but really felt like I grasped the concepts better after the simulation."

"Simple definition of PK."

Feedback on the Toxicology Session

"Very good overview of what is needed to start the different clinical development stages."

"Very good Workshop feedback on how to carefully interpret toxicology findings."

"I found this well-structured and very informative. Scott Boley did a fantastic job on toxicology."

"Great material. Well presented. The Workshop exemplified how to determine dosage. Too tired to get the most out of this session."

"Another excellent session and Workshop exercise."

"This will definitely change the way I look at risk mitigation

"I found this well structured and very informative. Scott Boley did a fantastic job on toxicology."

"Great material. Well presented. The Workshop exemplified how to determine dosage. Too tired to get the most out of this session."

"Another excellent session and Workshop exercise."

"This will definitely change the way I look at risk mitigation strategy prior to the FIH studies."

"How to calculate the starting dose in Phase 1." "Scott was great."

"Greater understanding of how doses are determined for early phase trials."

"It was helpful to learn how type of compound affects tox development path."

"Would like to hear more about toxicology of bio layer molecules."

"Best lecture of the first day. Liked simple rules for FIH dose. Complex issues made simple so those outside expertise have some framework."

"Enjoyed the review of how to develop development plan."

"Very good overview of small molecule vs biologic - learned a lot about small molecule development. Also good overview of differences for "chronic non-life threatening" vs acute life threatening approaches."

"Interesting review of tox for biopharmaceuticals."

"The human equivalence dose calculation table with be a tool I can refer back to again and again."

"The key differences between small molecules, biologics, and life-threatening vs non-life threatening diseases."

"Good session"

"Great session! Really enjoyed the toxicology workshop."

"The conversion formulas for animals to human."

"How to design toxicology studies from previous data."

"Very interesting session!"

"Toxicology session and workshop - thoroughly enjoyed."

"Very interesting session."

"How to design toxicology studies relevant to or leading to IND/CTA Phase 1/2."

"Very well laid out. Can use this as a checklist for myself."

"I really appreciated hearing about which tox studies are required in which situations. I feel like I can understand my tox colleagues efforts much better."

"Dose selection strategies and conversion tables."

Feedback on the Chemistry Manufacturing Controls Session

"Good overview and introduction of quality by design (QbD) -- also the importance of QTPP."

"It was great to hear mistakes not to make."

"Understood the increased amount of variability for biologics. Really liked the "scaling up" challenges description by Seshu: Building/ Country/Org."

"Great session, positioned importance clearly and in a digestible manner."

"Key points and how to avoid mistakes." "Good session."

"Fabulous! Brought great key messages for me to use." "That CMC can be quite fun. Excellent Faculty."

"I have a better appreciation for the variety of challenges respect to manufacturing - particularly the academia - industry transition."

"Good session."

"An excellent, engaging session." "Liked very much Biologics section." "Very informative."

"Education of CMC tasks, challenges, time needed, and complexity is very much needed by all the personnel involved in drug development."

"Very good coverage of a complex topic."

"Could be a bit less detailed to allow other sessions to have more time. This was excellent though!"

"Very nice presentations!"

"Increased appreciation for this function." "Very informative session."

"Both CMC sessions were great."

"Now I know why my Chemistry colleagues get so excited about process improvements!"

Feedback on the Clinical Session

"Workshop with statistical modeling was good."

"I learnt about the use of appropriate designs!"

I'll consider adaptive design for upcoming Phase 2 study." "I liked the format."

"Think, rethink and challenge myself / others to design "smart clinical trials."

"Use of the stats software was great. Should have spent more time on it."

"Dr. Chang's statistic program for Adaptive design was exceptionally useful for clinical designs."

"I have developed a much more comprehensive understanding of clinical trial design in conjunction with process development. All of this will enable me to make better decisions and ask the right questions."

"Very good explanation / examples of Trial Designs (Adaptive)."

"Interesting to learn how clinical trials are designed."

"Use of adaptive design. Better understanding of how to better design clinical trials."

Feedback on Day 2 Afternoon Session

"This was so helpful in bringing all of our learnings together - great session!"

"A strategic perspective of how to incorporate all aspects in a full program."

"Very interesting case." "This activity was excellent."

"The real-world development story is stirring. I am so impressed!"

"Even with limited CMC CMC expertise we could make useful comments."

"Good collaborative team work."

"An understanding of the challenges in the preclinical lead optimization phase."

"During the final reporting back was great to see the actual development unfold. Very well structured."

"Very good case! Very interesting to see the real-life

story." "A little bit of a struggle, but very productive."

Feedback on Final Session: Sending Out the Special Forces!

"The economic framework and holistic picture on the industry are crical for participants to understand drivers behind drug development trends."

"Understanding the major cost driver is clinical trial cost (Tuft's analysis)."

"The economic framework and holistic picture on the industry are critical for participants to understand drivers behind drug development trends."

Need for efficiency in our industry due to the cost of bringing a drug to market.

The key major take home message is "Think out of the box."

Great insight into the driving forces around the future directions of the industry.

"Interesting look at costs and collaborative opportunities. Adequate scope of due diligence and consequences of decisions."

"Tufts data provides nice call to action to plan to increase productivity."

"Great presenters"

"Very interesting. Right tempo."

"Interesting to have broad view of the industry."

"This session really completes our learning on drug

development." "Very informative session."

"The follow-on timings for "me-toos" was a new datapoint for me. Will use in financial modeling.

Laptops and iPads

All participants must ensure that they bring a laptop or an iPad with them to the Boot Camp. Participants will be provided the Briefing Book in an electronic format. The electronic Briefing Book will also be available on a server for viewing for those that want to bring their iPads.

At the request of past participants that we move into the 21st Century, save the trees, and provide everything electronically, hard copies of the materials will not be provided.

Last Date for Registration

The last date for registration is the 15th of March 2024. Please register as early as possible to gain the benefit of the Pre- Boot Camp preparation process. Substitutions for registrations that cannot be fulfilled will be subject to a supplementary fee after the 31st of December 2023. Registration after this date may be feasible, depending on space, but will be subject to an $800 late registration supplementary fee, in addition to the registration fee.

VIRTUAL Participation in Real-time

There is no content on demand. The sessions are not recorded as they occur to ensure all discussions remain confidential. All participants take the training in real time.

Refunds and Cancellations

We regret that after registration, funds cannot be refunded for any reason. One substitution will be permitted for one paid registration, up to 31 December 2023. Additional substitutions can be made up to 31 January 2024, for a supplement of 500 USD. After 31 January 2024, we regret that no further substitutions will be feasible. Registrations cannot be moved to future years, for any reason.

Faculty

The following Faculty are representative for the 2024 Drug Development Boot Camp®. Changes may be necessary due to scheduling and personal conflicts nearer the Drug Development Boot Camp®.

Scott E. Boley, Ph.D., DABT., Senior Scientific Advisor, Safety Assessment, Altasciences

Areas to be covered: Preclinical Development and Toxicology

Scott E. Boley, Ph.D., DABT, joined Sinclair Research Center in June of 2018 as Vice President of Toxicology. He received his doctorate in biochemistry and environmental toxicology from Michigan State University, where his research focused on the malignant transformation of human cells using tissue culture. His postdoctoral work, conducted at CIIT Centers for Health Research (Research Triangle Park, North Carolina), involved the use of transgenic mice and molecular biology to examine tumors induced in these mice for characteristics common to human tumor formation. He then went to Eli Lilly and Company (Greenfield, IN) as a research scientist in nonclinical safety assessment, where he developed the nonclinical strategy for novel oncological and neurological compounds. In addition to designing and managing investigational, screening, and animal studies required for regulatory submission, he authored the toxicology sections for INDs and for clinical investigator brochures. He then moved on to MPI Research (Mattawan MI) where he started as a Study Director in General Toxicology, and then moved through various managerial roles including Senior Director of General Toxicology and Senior Scientific Advisor where he worked with a variety of Sponsors in evaluating the nonclinical needs of the program for their therapeutic. He now serves as Senior Vice President of Research and Operations at Sinclair Research Center (Auxvasse, MO).

Joseph A. DiMasi, Ph.D., Director of Economic Analysis, Tufts Center for the Study of Drug Development, Tufts University of Boston, MA

Areas to be covered: Latest pharmaceutical industry benchmarking data

Dr. DiMasi is Director of Economic Analysis at the Tufts Center for the Study of Drug Development. The Center is an independent non-profit multidisciplinary research organization affiliated with Tufts University that is committed to the exploration of scientific, economic, legal, and public policy issues related to pharmaceutical and biotechnology research, development, and regulation throughout the world. Dr. DiMasi serves on the editorial board of Therapeutic Innovation and Regulatory Science, and has served on the editorial boards of the Journal of Research in Pharmaceutical Economics, and the Journal of Pharmaceutical Finance, Economics & Policy. Dr. DiMasi has published in a wide variety of economic, medical, and scientific journals, and has presented his research at numerous professional and industry conferences. Dr. DiMasi testified before the U.S. Congress in hearings leading up to the FDA Modernization Act of 1997 and reauthorization of the Prescription Drug User Fee Act.

Yasha Dwivedi, Director, Supply Chain Management, Alkermes Inc.

Areas to be covered: Project Management

Yasha has extensive experience in managing compounds in different drug-development stages as well as therapeutic areas. Prior to completing her Master's in Bioengineering, Yasha worked for Argonne National Lab, Rush University Medical Center and Roche Diagnostics. Over the last decade, Yasha has worked for Parexel, Takeda, Vertex and most recently at Alkermes, Inc.

Katarina Ilic M.D., Ph.D., MPH, Recently Senior Medical Director, Clinical Science, at Rare, Genetics and Hematology Therapeutic Area Unit, Takeda

Areas to be covered: Clinical Strategic

Katarina Ilic, MD MSc PhD MPH, most recently Senior Medical Director, Clinical Science, at Rare, Genetics and Hematology Therapeutic Area Unit (TAU) at Takeda, is a safety physician, pharmacologist/clinical pharmacologist and a pharmacoepidemiologist with extensive experience in clinical development, drug safety, clinical safety, and pharmacovigilance. Prior to joining Shire, which was acquired by Takeda, Katarina worked in Drug Safety as a Senior and an Executive Medical Director, Head of Drug Safety. As an active participant in the International Society of Pharmacovigilance (ISoP) for more than 10 years, Dr. Ilic was appointed the title of ISoP fellow (FISoP). Before working in the pharmaceutical industry, Katarina was a professor at the Department of Pharmacology at the School of Pharmacy, University of Belgrade and an expert appointed by the Ministry of Health of the Republic of Serbia. She published manuscripts in peer-reviewed journals and regularly serves as reviewer.

Carlos R. Langezaal, Ph.D., Senior Director, Regulatory Affairs, Premier Research

Areas to be covered: Regulatory Affairs

Carlos R. Langezaal, Ph.D., is Senior Director, Regulatory Affairs at Premier Research. Previously, he worked at BMS/Cellgene, Eisai, Sanofi-Aventis, J&J PRD, Schering-Plough, Core Technologies, Eli Lilly and Baxter in various therapeutic areas, including oncology, allergy, respiratory and internal medicine. He has more than 30 years of experience in regulatory affairs, having worked in the device, device/drug combination products, CMC and Clinical/ non-Clinical development areas primarily with a global focus. In addition, he is an active volunteer in The Organisation for Professionals in Regulatory Affairs (TOPRA).

Colin Maclachlan, M.A. (Hons.), M.Litt. in Terrorism [Guest Speaker]

Areas to be covered: Sending Out the Special Forces®; Leadership; Resilience

Colin Maclachlan, star of Channel Four's captivating reality TV drama *SAS: Who Dares Wins* and Channel 5's '*Secrets of the SAS'* is an operator with over 25 years of security and risk related experience.

Colin joined the army in 1989 and after 9 years in the Royal Scots passed selection first time aged 23 into 22 SAS. Colin was fortunate enough to have been involved in some of the more high profile and daring missions of the recent period. Only a handful of men have been involved in hostage negotiations, hostage rescue and been a hostage themselves and Colin is one of them. He waded through stinking swamps in Sierra Leone in West Africa to hunt down the West Side Boys, a guerilla gang holding five British soldiers hostage. It was a mission so daring and dangerous they nicknamed it Operation Certain Death. The SAS recce teams secured the hostages' building and neutralised any West Side Boys prior to the main assault arriving and secured the prison building before the rest of the unit arrived wiping out the terrorists in 2000.

He was also the first sniper on the scene when a hijacked Afghan flight with 180 passengers landed in London in the same year, sparking a stand-off that lasted four days and was the longest standing hostage siege on UK soil to date. But four years later Colin found himself on the other side of a rescue mission after he was taken hostage in the Iraqi city of Basra. Blindfolded, battered and stripped naked, he felt a gun pressed to his head and heard them pull the trigger in what was a mock execution. Father-of-two Colin only survived long enough for British troops to rescue him because the terrorists who held him wanted to film his suffering in a propaganda video before they executed him.

Colin left the SAS shortly after doing an exchange programme with both Delta Force and Seal Team 6 and after doing security consultancy for the Saudi Royal Family, A-List Celebrities and US Media Networks decided to fund himself through university where he attained a First Class MA (Hons.) in History from Edinburgh University and an M.Litt in Terrorism from St. Andrews University. Colin is now involved in TV, Book, Radio and Video Games and also does a lot with charity being involved as Ambassador for the Lee Rigby Foundation, Pilgrim Bandits and NSPCC among others. He has also just founded his own charity *Who Dares Cares* that aims to link and support veterans as well as others that encounter stress.

Having had both an exciting and varied career, Colin is an excellent speaker on a wide variety of topics including Resilience, Teamwork, Leadership, Risk, Motivation, Conflict Resolution, Change Management, Negotiation and Performance. He is also an experienced presenter and host for events and is co-founder of Stoic Events.

John Moscariello, Ph.D., Vice President, Viral Vector and Gene Editing Process Development, Bristol Myers Squibb

Areas to be covered: Chemistry Manufacturing Controls, Biologics and Cellular Therapies

John Moscariello currently serves as Senior Director of Viral Vector and Gene Editing Process Development at Juno Therapeutics, a Celgene Company. Prior to that, he was the Vice President of Process Development at AGC Biologics (formerly CMC Biologics) where his team was responsible cell line development, upstream and downstream process development, analytical and formulation development, and technical support for AGC Biologic's commercial manufacturing facility and supported development activities from generating processes for Toxicology/Phase 1 supply up to and including commercialization and post-approval process support. John is very active in the biotechnology community. He is on the Scientific Advisory Board for various conferences, including the BioProcess International conference series, and the CBI conference series on achieving efficient facilities and the next frontier of single-use technologies. John obtained his Ph.D. in Chemical and Biological Engineering from the University of Wisconsin-Madison, and his B.Eng. in Chemical Engineering from the University of Delaware.

Tom J. Parry, Ph.D., M.B.A., BCMAS, Chief Scientific Officer, NeuroTrauma Sciences LLC

Areas to be covered: Preclinical Efficacy and Toxicology, Case Studies

Tom J. Parry, PhD, MBA, BCMAS is Sr. VP Research and Early Development at NeuroTrauma Sciences, LLC (NTS), joining the company in April 2021. Tom is also Founder and Principal of Skyline Biopharma, LLC, a biopharmaceutical development consulting group, established in 2017. Prior to his role at NTS, Tom was VP of Research and Early Development at Ovid Therapeutics. Over his career, Dr. Parry served various pharmacology as well as toxicology leadership and scientific roles in multiple biotechnology companies including Acorda Therapeutics, Ribozyme Pharmaceuticals (aka Sirna Therapeutics acquired by Merck) and Human Genome Sciences (acquired by GSK), where he supported drug discovery and development regulatory submissions. Dr. Parry also served as a Principal Scientist at Johnson and Johnson where he worked on multiple products in areas of drug-device combinations, cardiovascular and metabolic disease and led a small group supporting cardiovascular safety screening.

Over his 25+ year biopharmaceutical career, Dr. Parry has obtained research grants, patents, authored/co-authored numerous peer-reviewed publications and serves on multiple NIH SBIR study sections. In addition to his biopharmaceutical company roles, Dr. Parry serves as an adjunct faculty member at Temple University School of Medicine and School of Pharmacy where he regularly teaches a graduate course in Pharmaceutical Biotechnology. Dr. Parry received a B.S. in Chemistry from Moravian College, a Ph.D. in Pharmacology from Temple University and was a post- doctoral fellow in Pharmacology/Psychiatry at the University of Pennsylvania. Dr. Parry also serves on the Executive and Program Committee and served as Chair of the Division of Drug Discovery and Development of ASPET.

John J. Piwinski, Ph.D., JJPiwinski Pharma Consulting, LLC

Areas to be covered: Chemistry/Medicinal Chemistry/Drug Discovery; Co-chair of the Day 2 Workshop Session

John J. Piwinski has extensive expertise in small molecule drug discovery with over 39 years of experience in medicinal chemistry. During his career, he oversaw discovery programs in chemistry from project initiation to delivery of candidates for clinical development. He received his B.S. degree in Chemistry and Biochemistry from the State University of New York at Stony Brook in 1976 and his Ph.D. in Organic Chemistry from Yale University in 1980. He then joined Revlon Health Care as a Senior Scientist working in the cardiovascular diseases area. In 1983 he moved to Schering-Plough where he worked in the respiratory diseases group.

At Schering he held positions of increasing responsibility and eventually oversaw Chemical Research as Vice President from 1999 to 2003 and Group Vice President from 2004 to 2008. In this position he was responsible for overseeing drug discovery in chemistry in Kenilworth, New Jersey in the areas of respiratory, inflammation, cardiovascular, CNS, oncology and infectious diseases. In 2008 he became the Site Head and Group Vice President of Schering-Plough's Cambridge, Massachusetts site. Research at the site focused on medicinal chemistry, affinity-based screening and optimization, bioNMR, protein science and biologics. Merck acquired Schering-Plough in 2009 and continued to operate the Cambridge site until the end of 2010. He currently consults in the areas of medicinal chemistry and drug discovery, including small molecule lead discovery and optimization. In this role he has consulted with numerous companies, which included conducting program consulting, due diligences and patent work. He has presented numerous talks at scientific meetings and has approximately 150 published research papers, abstracts and approved U.S. patents. He is a member of the Innovation Support Center Advisory Panel for the Harrington Discovery Institute, a Scientific Advisory Board Member for the Center to Develop Therapeutic Countermeasures to Treat Bacterial Agents at Rutgers University, and a member for the Institute of Chemical Biology & Drug Discovery Advisory Board at Stony Brook University. In recognition of his accomplishments, he received the North Jersey American Chemical Society (NJACS) Lifetime Achievement Award in 2013.

Pauline Silverman, Strategic Marketing Consultant

Areas to be covered: Commercial Session Panel Member; Chair of the Final Session

Pauline Silverman is a globally experienced marketer with 20+ years of experience and she is currently an independent consultant providing interim management and strategic marketing consultancy to companies and agencies in the over-the-counter pharmaceutical and consumer packaged goods industries.

In her previous corporate life, she worked at GlaxoSmithKline Consumer Healthcare (GSK) where she progressed in positions of increasing responsibility from Brand Manager to Director, in-market in the U.S., Germany, and the U.K. and in leading assignments for LATAM, Greater China and S.E. Asia. Her tenure at GSK included responsibility for the global Adhesive Segment of the Denture Care Portfolio, the Oral Care portfolio in North & West Europe, and multiple consumer healthcare brands in the U.S. Prior to GSK, Pauline worked in Canada for the Block Drug Co. on dermatological and digestive health OTC brands.

Pauline's passion for marketing comes from the satisfaction of uncovering insights to overcome barriers along the customer journey. She is skilled in the full range of consumer and healthcare professional marketing competences with accomplishments that include almost tripling the 3-Year net sales CAGR of

Sensodyne in the US, directing transformative innovation such as the launch of the acid erosion segment and its solution Pronamel in the highly competitive US toothpaste market, developing an award winning strategy for the Biotene Dry Mouth portfolio, and catapulting Abreva to the #1 brand in the US cold sore category within its first year of launch.

With experience living and working in multiple geographies, Pauline brings an international perspective to her work with an appreciation for the value of diversity in thoughts, opinions and cultures. Pauline has an MBA from the University of Pittsburgh, The Joseph M. Katz Graduate School of Business.

Ambarish Singh, Ph.D., Head, Global Regulatory Sciences, Morphosys

Areas to be covered: Chemistry Manufacturing Controls (small molecules)

Dr. Ambarish Singh is a skilled small-molecule regulatory CMC strategist with experience in worldwide filing of pre- and post-approval regulatory documents and has led/participated in several Health Authority (HA) interactions. Prior to moving into the Regulatory-CMC department within the Bristol Myers Squibb Company, Ambarish was in the Chemical Development department, where he contributed to the chemical process development of numerous commercial products. Ambarish is currently at Constellation Pharmaceuticals (a MorphoSys company), serving as the head of Regulatory Science and Technology, where he is applying his regulatory and technical knowledge in providing strategic guidance on the preparation of CMC documents for regulatory filings. Ambarish holds a PhD in Organic Chemistry from the State University of New York at Stony Brook. He served as a post-doctoral fellow at the Fox Chase Cancer Center, Philadelphia and Memorial Sloan Kettering Cancer Center, New York.

Lorna Speid, B.Pharm.(Hons.)., M.R.Pharm.S., Ph.D., RAC, Speid & Associates, Inc., Founder and Chair, Drug Development Boot Camp®

Areas to be covered: Global and Strategic Regulatory Affairs, Chemistry Manufacturing Controls, Clinical Strategic, and Commercial Workshop

Lorna is the Founder and Chair of the Drug Development Boot Camp. She is an expert in global and strategic regulatory affairs, and new medicine development. Dr. Speid has an excellent track record of success in regulatory affairs, and is considered an expert by her peers. As an expert regulatory affairs consultant, Dr. Speid works with small and large pharmaceutical companies, assisting them at all stages of the drug development process. She has experience working on US, European, international and global strategic regulatory affairs. Dr. Speid has experience with many therapeutic areas, including oncology (solid tumors and hematological cancers), diabetes (Type 1 and Type 2), obesity, dermatology, transplantation, lupus, bone, women's health (hormone replacement therapy and osteoporosis), Sickle Cell Disease, and pulmonary diseases including asthma and COPD. Lorna is an expert in new medicine development for rare and neglected diseases, including the use of appropriate regulatory processes.

For more information on Dr. Speid's expertise, see **Chair Bio**.

Michael V. Templin, PhD, DABT; Director, Scientific Advisory Services, Charles River Laboratories

Areas to be covered: Toxicological Evaluation of Impurities (CMC)

Dr. Templin has over 20 years of experience in nonclinical/clinical drug development; with expertise in nonclinical toxicology, pharmacology, pharmacokinetics, and pharmacodynamics; and a proven track record for transitioning drug candidates from research into development programs. He has worked in the CRO field to provide scientific and program guidance for nonclinical development; provide advice to strengthen and/or accelerate nonclinical development programs; and enhance scientific rigor and regulatory compliance for biotech and pharma clients. Pharmaceutical development experience includes programs for gene therapy,

biologics, nucleic acid-based compounds, proteins/peptides, and small molecules. Industry experiences have ranged from start-up biotechnology to mid-sized pharma companies. In his current role, Michael provides scientific and nonclinical program management expertise and guidance to current and prospective Sponsors engaged in the discovery and development of therapeutics utilizing Charles River Laboratories' (CRL) broad portfolio of discovery and safety assessment services.

Zhaoyang Teng, Ph.D. Associate Director of Biostatistics, Servier Pharmaceuticals

Areas to be covered: Adaptive Clinical Study Designs

Dr. Teng is currently the Associate Director of Biostatistics at Servier Pharmaceuticals, which is a privately held international pharmaceutical company, governed by an independent non-profit foundation. He has extensive experience in all phases of oncology drug development (Phase I to IV) including global NDA/sNDA regulatory submissions. At Servier, he provides statistical expertise and strategic input on drug development plans, critical Go/No-Go decisions and global regulatory submissions for various disease areas, including oncology and CNS. Prior to joining Servier, he worked at Takeda Pharmaceuticals for several years. Dr. Teng received his PhD in Biostatistics from Boston University. His research interests include adaptive clinical trial designs, seamless phase 2/3 study designs, model-based meta-analyses and multi-regional clinical trials. He has published more than 15 papers in peer-reviewed statistical and medical journals or book chapters, with approximately10 of them as first author. He is also an active member in SCT (Society for Clinical Trial), and ICSA (International Chinese Statistics Association). His goal is to serve the biostatistics related professional community.

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