The only clinical outsourcing platform for the biotech, pharma and medical device companies in Israel

Speakers in 2018

Sachi Norman, Chief Medical Officer, **Life Bond**
Ayelet Levanon, Associate Director, Global Clinical Operations, **Janssen**
Illana Gozes, Chief Science Officer, **Coronis Neurosciences**
Liora Bosch, Bio-Statistician and EDC expert, **Omrix Biopharmaceuticals, Johnson & Johnson**
Marina Weisflender, Head of Clinical & Regulatory Affairs, **Amorphical**
Pnina Strauss-Levy, Previously VP Clinical & Regulatory Affairs, **Intec Pharmaceuticals**
Nahum Ferera, CEO & Co – Founder of EyeYon Medical, **EyeYon Medical**
Adar Shani, VP Clinical & RA, **Nuvo Group**
Tali Amir-Azulay, Director of Operations, **Neuroderm**
Moshe Golan, President and CEO, **3QBD**
Keren David-Zarbiv, Director of Clinical Affairs, **MediWound**
Dror Chevion, CEO, **Concenter Bio Pharma**
Sharon Castro, Director of Clinical Trials, **Kamada**
Liran Korine, Director of Clinical Affairs, **ElMindA**
Stephen Marx, CEO, **Marx Technologies**
Ron Nitzan, VP QA/RA, **Keystone Heart**
Vardit Segal, VP Clinical & Regulatory Affairs, **Allium Medical**
Bernard Green, CSO, **Semorex Inc**
Nitza Shoham, VP, Clinical & RA, **Valtech Cardio**
Irit Glicko-Kabir, Senior Director Clinical Development, **BioLineRx**
Israel Citron, VP QA & RA, **Aspect Imaging**
Catherine Ela, Head of the Clinical Trial Department, **Ministry of Health**
Dr. Yafit Stark, Vice President, Chief Clinical Officer and Head of Oncology, Emerging Therapeutic Areas & Biogenetics Innovative R&D**, Teva**
Sharon Shachar, Director of Quality & Regulation, **InspireMD**
Mark Gosnell, Medical Device Consultant, **Boston Biomedical Associates**

Further Information

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	Programme Day One **20th March 2018**
7:45	*Registration and Refreshments*
8:20	*Chairman's Opening Remarks*
8:30	**Keynote Presentation** **Home Advantage: Assessing Israel's competitive landscape to underpin and sustain your competitive advantage** • Evaluating the competitive landscape within Israeli industry to illustrate growing competitive nature of sector, highlighting key R&D gaps to capitalise upon • Illustrating latest developments within industry to determine Israel's 'home competitive advantage' to explore how entrepreneurism can be further leveraged • Establishing areas that quickly becoming saturated to explore opportunities for unique products • Reviewing importance of differentiation techniques within both product and process innovation to increase product value and market positioning • Highlighting key opportunities within patient recruitment within Israel to assess benefits of clinical trials within the country **Dr. Yafit Stark, Vice President, Chief Clinical Officer and Head of Oncology, Emerging Therapeutic Areas & Biogenerics Innovative R&D, Teva**
9:00	**Early Feasibility Studies (EFS) in the United States** 1. EFS program overview 2. Which devices are eligible for EFS pathway 3. EFS process: pre-sub through IDE approval 4. Tips for success **Mark Gosnell, Medical Device Consultant, Boston Biomedical Associates**
	Sourcing optimal vendors to enable accurate and successful trials
9:30	**Fail to Prepare, Prepare to Fail: Exploring key preparation considerations of outsourcing clinical trials to ensure seamless procedures** • Investigating outsourcing streams to establish vertically integration opportunities, in order to cut costs • Evaluating clinical trial processes to ensure optimal resource allocation • Determining difficulties of procuring vendors to establish demands for flexible budgets and timelines • Illustrating mapping techniques to ensure operations achieve deadlines • Highlighting changing regulations and guidelines between countries to prepare for

	challenges in clinical trials **Sharon Shachar, Director of Quality and Regulation, InspireMD**
10:00	**Agenda Highlight** **Q&A session with the Ministry of Health** **Detailing regulatory changes within the industry to assess changing needs and direction of processes, to ensure compliant procedures within clinical trials** **10:00 – 10:15** • Outlining new regulations to explore impacts of changing requirements and guidelines on the industry to allow better preparation • Highlighting implications of implemented changes to forecast increasing pressures and mitigate concerns • Exploring outcomes for non-compliant activities to determine impact on drug development and company reputation **10:15 – 10:30 Q&A** Question from the audience for the Ministry of Health **Catherine Ela, Head of the Clinical Trial Department, Ministry of Health**
10:30	*Networking and Refreshments*
11:00	**Panel Discussion** **Attaining an Optimal Fit: Evaluating vendor procurement and relationships to enable successful studies** • Identifying internal resources and establishing key company competencies, to explore areas in need of outsourcing • Illustrating optimal partnerships that align with company culture to ensure seamless clinical trial operations • Evaluating how exceptional partnerships ensure optimal collaboration to ensure long lasting and successful relationships • Exploring best practises in environment scanning to ensure vendor partnerships that best fit your operations • Discussing implications of poor Sponsor-CRO planning to highlight implications on vendor relationships **Sharon Shachar, Director of Quality and Regulation, InspireMD** **Keren David-Zarbiv, Director of Clinical Affairs, MediWound** **Ayelet Levanon, Associate Director - Global Clinical Operations, Janssen** **Adar Shani, VP Clinical & RA, Nuvo Group**

11:30	Session reserved for **PRA Health Sciences**
International procurement of clinical trials and foreign studies	
12:00	**Part One** **12:00-12:15 Discussing international studies in theory to provide a deep-seated overview of key benefits in foreign markets** • Assessing fundamental differences in outsourcing local vs international studies to create an appreciation for varying levels of bureaucratic processes and contrasting challenges • Illustrating operational differences with Europe and USA to evaluate how to ensure timely studies • Highlighting pivotal pros and cons of international studies to underpin efficiency difficulties and best operational techniques • Investigating management inefficiencies between countries to underpin advantages of outsourcing abroad • Illustrating outsourcing contracts with CROs in China to underpin opportunities and challenges and gauge a greater understanding of key cost and time implications on drug development procedures **Irit Glicko-Kabir, Senior Director Clinical Development, BioLineRx** **Part Two** **12:15 – 12:30 Evaluating international studies in practice to establish successful foreign clinical trials** • Highlighting cultural differences to ensure optimal vendor management techniques • Assessing key preparation steps to ensure that optimal positioning with CROs is achieved to ensure maximum efficiency • Exploring management techniques to secure collection of accurate data in agreed time frame • Determining crucial communication techniques with principal investigators to ensure responsibility and duties are met **Nahum Ferera, Chief Science Officer, EyeYon Medical** **12:30 – 12:40 International study Q&A with the audience** **Irit Glicko-Kabir, Senior Director Clinical Development, BioLineRx** **Nahum Ferera, Chief Science Officer, EyeYon Medical**
12:40	Session reserved for Genae Spotlight Partner
12:55	*Lunch and Networking*
Key vendor management techniques and tools	

14:00	**Panel Discussion** **Cool, Cohesive and Controlled: Establishing control retention methods to place upon CROs to ensure timely clinical trials** • Highlighting biggest hardships and conflicts of interest when partnering with CROs, to alleviate clashes • Evaluating implications of conflicts to illustrate ramifications on financial resources • Assessing how best to implement payment milestones and invoice strategies to establish control of partnership • Exploring options and benefits of outsourcing audits to secure disciplined trials • Investigating varying needs of control over different vendors to ensure superior resource allocation **Adar Shani, VP Clinical & RA, Nuvo Group** **Pnina Strauss-Levy, VP Clinical & Regulatory Affairs, Intec Pharmaceuticals** **Israel Citron, VP QA & RA, Aspect Imaging**
14:30	**Mother of all Management Methods: Establishing key performance metrics to ensure timely studies within budget** • Highlighting critical issues with CROs who over promise and under deliver to underpin the need for sharper management techniques • Evaluating best utilisation of performance measures to enhance CRO productivity and ensure efficient operations of studies • Determining events if stringent mechanisms are not applied to studies to appreciate implications and benefits of metrics • Illustrating major risks of poor performance metrics strategies to ensure collaborative studies • Highlighting how performance measurement will improve relationships with CROs to enable best sponsor-vendor relationships **Irit Glicko-Kabir, Senior Director Clinical Development, Biolinerx**
15:00	*Afternoon refreshments and networking*
15:30	**Panel Discussion:** **Exploring contrasting characteristics between sponsors to ensure successful studies to clarify ambiguous variables** • Assessing varying attributes between drug development companies to explore options in size of CRO sourced • Exploring small contractors to illustrate potential needs for tick transferring processes • Investigating impacts of tick transfer processes to determine value of small vendors and mitigate inefficiencies in new product development

	• Determining crucial management techniques for large CROs to ensure they do not take advantage of sponsors • Exploring options to integrate both a small and large CRO, to utilise their expertise for different services and implement a competitive business strategy **Professor Illana Gozes, Chief Science Officer, Coronis Neurosciences** **Dror Chevion, CEO, Concenter Bio Pharma** **Irit Glicko-Kabir, Senior Director Clinical Development, Biolinerx**
16:00	**Communication Conundrums: Establishing how best to communicate with your CRO to ensure efficient managerial methods to secure successful clinical trials** • Highlighting excellent sponsor-CRO communication strategies to investigate levels of resource allocation • Illustrating transparent communication techniques that will foster mutual sponsor-CRO trust, to enable close collaboration within studies and long lasting relationships • Exploring various channels of communication to underpin united strategies that ensure clinical trials are timely • Investigating effects of poor communication strategies to mitigate negative impacts on CRO relationships • Determining implications of too much communication to establish effect on timeframes **Tali Amir-Azulay, Director of Operations, Neuroderm**
16:30	**Managing Multiple CROs: Exploring multi CRO management to ensure successful clinical trials** • Discussing wide ranges of activities that can be outsourced to lean operations • Exploring multi-vendor management strategies to administer better control of procedures • Revisiting changes within regulatory environment to underpin forthcoming challenges and opportunities of managing EU and USA vendors • Evaluating placements of resources to ensure stringent process in an affordable and timely manner • Recalling top communication techniques to ensure efficient portfolio management and reap time efficiencies **Keren David-Zarbiv, Director of Clinical Affairs, MediWound**
17:00	*Chairman's summation and close of day one*

Programme Day Two **21st March 2018**		
8:00	*Registration and Refreshments*	
8:20	*Chair's Opening Remarks*	*Chair's Opening Remarks*
	Medical Device Stream	**Biotech Stream**
8:30	**Complications with CE: Highlighting FDA enforcements for attaining CE marked products, to establish best practices in achieving certification** • Highlighting stringent enforcements from Medical Device Regulators to create an awareness for increasingly arduous and lengthy obstacles • Assessing demands from authorities and ethics committees when conducting new Medical Device studies to appreciate crucial difficulties in achieving CE certified products • Illustrating technical and documentation difficulties to mitigate impact on timeframes • Discussing timelines to evaluate subsequent increased timespan of processes with the MDR and financial risk • Underpinning best methods to get FDA approval for new medical to enable an efficient entry to market **Vardit Segal, VP Clinical & Regulatory Affairs, Allium Medical**	**Challenges of Small Companies: Lessons Learnt from a biotech perspective; where, what and how to outsource CROs efficiently** • Defining different types of start-ups to discuss technologies and differing levels of capabilities/resources and funding • Highlighting the need for a CRO that truly understands your drug development concept to ensure a timely and accurate study • Evaluating implications upon quality if poorly suited CRO is contracted, to establish strategic methods of outsourcing • Creating an awareness of un-kept promises from CRO to highlight lessons learnt and best recruitment strategies. • Discussing specialist CROs to illustrate best fit in terms of equipment and expertise **Stephen Marx, CEO, Marx Technologies**
9:00	**Partnering Up: Reviewing medical device studies to evaluate need for product expertise for successful trials** • Discussing needs for specialist medical device CROs to underpin key efficiency opportunities within clinical trial studies • Highlighting key benefits of	**Not EU Again: Identifying key opportunities and mitigating challenges in new EU regulations to alleviate impact on budgets** • Highlighting key changes in regulatory guidelines within European confidentiality directives to better prepare for future plausible challenges • Assessing implications new regulations

	utilising specialist vendor to ensure timely procedures • Illustrating fundamental CRO sourcing techniques to secure the right partner and enable specialised studies • Investigating specialist expertise to highlight implications on accuracy of medical trial studies if not sourced diligently • Evaluating stringent CRO recruitment strategies to effectively understand truths behind pitches, to ensure promises are kept throughout medical device studies **Sachi Norman, Chief Medical Officer, Life Bond**	could bring in attaining FDA approval to mitigate further strain on budgets and timespans • Illustrating strategies to ensure protocols achieve FDA approval in light of new directives, to efficiently mitigate financial risk and shorten process of ratification • Evaluating benefits of incorporating authorities within studies to enable transparent procedures, to ensure seamless clinical development procedures • Revisiting outsourcing models to determine benefits of procuring protocol experts and ensure compliant studies **Marina Weisflender, Head of Clinical & Regulatory Affairs, Amorphical**
9:30	Session reserved for **Event Sponsor**	Session reserved for **Event Sponsor**
10:00	**Quality vs Costs: Exploring needs to strike optimal balance between quality and cost of outsourcing clinical trials to achieve first-rate business strategies** • Highlighting increasing need for studies of highest quality to enable seamless authorisation of drug developments • Discussing results of clinical trials against budget restricting to create greater appreciations for quality and accurate data collection and ensure accreditation of drug development • Evaluating financial risk against quality need to establish an optimal balance that will enable visible resource allocation strategies • Illustrating outsourcing	**Q&A Shall we or Shan't we? Outlining blessings and drawbacks of outsourcing clinical trials within Israel to assess degree of complementation** • Exploring Israel's varied portfolio of services to evaluate opportunities for clinical trials • Assessing changes in regulations to highlight time impediments and financial risk on studies • Examining diversified patient population within Israel to establish key quality benefits of conducting trials within home country • Evaluating benefit and pitfalls of managing vendors in close proximity **Dror Chevion, CEO, Concenter Bio Pharma**

	opportunities that enhance quality of studies to ensure accurate data • Investigating relationships between implementing increased quality standards and timeframes to ensure efficient and effective clinical trials **Nitza Shoham, VP, Clinical & RA, Valtech Cardio**	
10:30	*Morning Refreshments and Networking*	
	Medical Device Stream	**Biotech Stream**
11:00	**Quality Qualms: Exploring need for quality within medical device studies to ensure controlled timeframes** • Assessing early stage development of medical devices to explore key product strategy considerations that ensure optimal outsourcing studies • Discussing needs for increased short-term flexibility in medical device advancement to enable focused long-term approach to clinical trials • Highlighting benefits of specialist vendors to establish top quality studies • Revisiting outsourcing strategies that enable partnerships with top quality CROs to mitigate financial risk • Appreciating quality hindrances during clinical trials, such as issues with patient recruitment, to establish realistic timelines and budgets **Ron Nitzan, Vice President of Quatliy Assurance and Regulatory Affairs, Keystone Heart**	**Exploring methods to best manage third parties within investigator integrated researched clinical trials** • Assessing best methods to effectively overseeing an investigator initiated trial • Illustrating implications of poor management of trials to highlight lessons learnt during procedures • Exploring third party investigators, especially physician to illustrate motivational techniques, to ensure timely studies and quick route to market • Determining whether sponsorship is a better option, to establish if this could result in more timely and efficient studies over government funded research studies • Establishing changes in MDR to evaluate impacts upon investigator integrated trials to forecast plausible challenges and changes in guidance **Professor Illana Gozes, Chief Science Officer, Coronis Neurosciences**

11:30	**Staff Motivation: Establishing strategies in which to drive staff to control the speed of clinical trials** • Highlighting areas of inefficiencies during clinical trials to underpin increasing need to motivate staff to ensure timely studies • Assessing management techniques to motivate staff to enable timely studies • Painting the bigger picture to illustrate constraints of patient recruitment within clinical trials to reassess and set realistic timelines and budgets • Pinpointing areas of flexibility within medical centres to highlight potential for increased procedure efficiencies • Exploring key methods of collaboration with physicians, to highlight communication techniques that motivate staff to ensure a cohesive and accurate study **Liran Korine, Director of Clinical Affairs, ElMindA**	**Collaboration Capacity: Highlighting medical centre collaboration strategies to ensure accurate and credible studies** • Illustrating mechanisms to co-ordinate medical centres during trials to appreciate how to escalate on a national level and help mitigate issues of internal politics within procedure • Assessing duties of physicians within medical centres to highlight their varying pressures, and attain a high level of empathy • Exploring best methods for collaborating with physicians to underpin strategies in which to motivate them on studies • Detailing key channels to adopt when communicating with physicians to further inspire them on your study to control speed of clinical trial • Evaluating implications of demotivated staff to illustrate small management tools can reap long term benefits **Sharon Castro, Director of Clinical Trials, Kamada**
12:00	**Negotiating with CROs: Establishing top techniques to secure cost effective clinical trials** • Highlighting growing needs for superior negotiation techniques with vendors to secure improved deals and mitigate financial risk • Illustrating benefits and pitfalls of solid negotiation methods to underpin the sweet spot and mitigate hostile relationships • Discussing variations between	**Once emerging, now falling: Assessing FDA crack down on India to evaluate implication upon drug development studies and underpin financial impacts** • Exploring FDA investigations into contractors to forecast plausible futures on sponsors who geographically outsource third parties from India • Evaluating inspections to highlight likelihood of outcome, to assess the negative implications within quality

	CRO characteristics to create an appreciation for different negotiation strategies, to secure top deals • Exploring crucial negotiation strategies that will ensure superior arrangements with CROs to enable smooth procedures • Assessing key repercussion on commitment intention of CROs to illustrate subsequent gain of control over vendors to reap financial benefits **Moshe Golan, President and CEO, 3QBD**	when building relationships with CROs from India • Highlighting FDA actions with Indian clinical trial processes and the pitfalls with their drug development studies to underpin key concerns • Examining implications of folding, experienced and low cost outsourcers to illustrate effects on budgets and financial resource allocation • Discussing new emerging markets, such as China, to determine their reliability and credibility as partners and assess outsourcing potential in line with business strategy **Pnina Strauss-Levy, VP Clinical & Regulatory Affairs, Intec Pharmaceuticals**
13:30	*Lunch and Networking*	
13:30	**Q&A with Investor** **Need my Money? Here's how you get it.** ***A transparent view into key criteria investors seek when*** **13:30 – 13:45 Snippet from Investor** • Assessing key benchmarking tools utilised by investors and agencies to underpin bottom line investment criteria • Analysing Israel's competitive landscape to detail how differentiation can be achieved, to deliver uniqueness and secure a competitive advantage • Illustrating how new start-up companies can attain funding to help get product to market **13:15 – 13:30 Q&A Session with Investor** • Questions from the audience **Israel Citron, VP QA & RA, Aspect Imaging**	
14:00	**Q&A Session** **Financial Needs: A funding headache** ***Assessing strategies to raise funds and attain investment to ensure product development and attain a crucial market position*** • Assessing hardships of securing investment for developing new drugs explore	

	implications on industry landscape • Highlighting competition within the market for funding, to examine unique selling points of product to champion funding • Evaluating different methods of acquiring funding, from EU sponsorship to building relationships with private agencies, to illustrate options within the sector • Exploring methods to best convince an agency you are worth investment, to fast track development of your products • Examining key lessons learnt from pitches to investment agencies to illustrate best and worst approaches to gaining funding **Bernard Green, CSO, Semorex Inc**
14:30	*Afternoon Refreshments and Networking*
15:00	**Roundtables** Break-out sessions to allow smaller groups to discuss the most pertinent themes of the event in finer and more case study-driven detail. Delegates should leave these sessions equipped with practical solutions to key challenges.
RT1	**Home Advantage:** Determining where your true uniqueness lies to underpin competitive advantage
RT2	**Data Management: To outsource or to vertically integrate?** Assessing key resources and capabilities to underpin a data strategy that aligns with your key competencies **Liora Bosch, Bio-Statistician and EDC expert, Omrix Biopharmaceuticals, Johnson &Johnson**
RT3	**Forecasting plausible futures:** Implications of new European regulation of privacy on Clinical Trials **Marina Weisflender**, **Head of Clinical & Regulatory Affairs**, **Amorphical**
RT4	**Negotiating with large CROs:** Establishing top techniques to secure cost effective clinical trials to secure best deals
16:30	***Chair's Closing Remarks and End of Conference***