

BIOTECH ATELIER 2.0

DRAFT AGENDA_v.12

08:00 – 09:00	Registration and Networking Coffee - good chance to talk with a lecturer, organizer or participant in case of early arrival
09:00 – 09:15	<p>Welcome and Opening of the BioTech Atelier <i>This is the second edition of Biotech Atelier after the great success of the event in 2018. We want to report the progress and look forward for 2020.</i></p> <p><i>Dr. Borislav Borissov PhD, Managing Director, Prescriptia</i> <i>Dr. Stanimir Hasurdjiev, Chairman of the Administrative board, Bulgarian Association for Personalized Medicine (BAPEMED)</i> <i>Peter Statev, Chairman of the Supervisory Board, Sofia Tech Park</i></p>
09.15 – 10.15	<p>Advanced therapy medicinal products (ATMPs) - ATMPs are the new hope and challenge for diagnosis, therapy, registration, pharmacovigilance. Pricing and reimbursement are big issues as well. The distinguished panelists will elaborate topics related to ATMPs in the EU and Bulgaria and stimulate the guests for a fruitful discussion.</p> <p>Keynote Lecturer - <u>Prof. Dr. Mondher Thoumi, President and Founder, Creativ-Ceutical</u></p> <ol style="list-style-type: none"> 1. Magda Chlebus, Executive Director, Science Policy and Regulatory Affairs, EFPIA 2. Dr. Borislav Borissov, Managing Director, Prescriptia 3. Prof. Dr. Steffen Thirstrup, Director, NDA Regulatory Advisory Board, NDA Advisory Services Ltd. 4. Peter Kapitein, President and Patient Advocate, Inspire2Live 5. Liliya Evtimova-Tichev, QA Validation Engineer, Lonza
10.15-10.30	<p>Presentation: Where does EFPIA plan to invest efforts in the new term of the EU parliament? <i>EFPIA has a slogan “ILLNESS NEVER SLEEPS, SO NEITHER CAN WE” and we hope to hear and understand this better</i></p> <p>Magda Chlebus, Executive Director, Science Policy and Regulatory Affairs, EFPIA</p>

10.30 – 11.30	<p>AI in Healthcare - Artificial Intelligence / AI/ is a hot topic in life sciences and healthcare. Could and would AI replace human intellect in diagnostic process and offer better treatment? Could we rely on AI for better analysis of the drug efficacy and safety? Has the AI already become a better tool for the registration process of drugs? The panel has the answers.</p> <p><u>Keynote Lecturer – Timm Pauli, Senior Director, Esubmission Services, Head of Regulatory Operations, PharmaLex</u></p> <ol style="list-style-type: none"> 1. Bruce Magill, Director of Business Development, Personalised Medicine & Connected Health EMEA, SAP 2. Dr. Mads Dalsgaard, Senior Vice President, Head of Experimental Medicine & Clinical Development, Lundbeck 3. Angela Velkova, Director of Communities and Strategic Relations, EMEA HIMSS Europe GmbH 4. Andrew Fried, Business Development Director, Healthcare and Life Sciences Europe, IBM 			
11.30-11.45	<p>Presentation: Developments in modern genetic testing – how far and how deep could we go?</p> <p>Paul Jones, Director, Population Genomics, Illumina</p>			
11.45 – 12.45	<p>The MEGA Project - the MEGA project has been started with a lot of enthusiasm and great expectations, but seems to be under prioritized now. Is this true or not? Where is Bulgaria in the MEGA project? The experts have answers and suggestions</p> <p><u>Keynote Lecturer – Bogi Eliassen, Associated Partner, Copenhagen Institute for Futures Studies</u></p> <ol style="list-style-type: none"> 1. Paul Jones, Director, Population Genomics, Illumina 2. Erik Steinfeldt, Director General, BBMRI-ERIC 3. Dr. Kate Witkowska, Commercial Partnerships Manager, Genomics England 4. Prof. Radka Kaneva, Executive Manager Molecular Medicine Center, Medical University of Sofia 5. Dr. Antonio Andreu, Scientific Director, EATRIS 			
12.45 – 13.15	<p>INTERVIEW</p> <p>Dr. Dimitar Georgiev, Founder and CEO Paralax Life Sciences</p> <p>with a distinguished guest of the Biotech Atelier</p>			
13.15 – 14.00	<p>Networking Lunch</p>			
14.00 – 15.00	<p>Access to Funding - Funding in Life sciences for both start-ups and mature companies is pretty difficult in Bulgaria? Why and how can this be improved?</p>	<p>Real World Evidence (RWE) - can RWE change definitely the pricing model? How IT technologies are involved in RWE</p>	<p>Personalized medicine in non-oncological disciplines – NM Genomix - Personalized medicine was long time related only to</p>	<p>Regional Partnerships – Regional partnerships are of paramount importance for business and science. However, Bulgaria is far behind</p>

	<p><u>Keynote – Jivko Ivanov,</u> <u>Managing Partner, Simbula</u></p> <ol style="list-style-type: none"> 1. Paul Gill, Managing Partner – Asia, Iota Omega Ventures Pte Ltd. 2. Gary Ashford, Partner, Harbottle and Lewis LLP 3. Milen Ivanov, CEO Angels Club 4. Peter Kapitein, President and Patient Advocate, Inspire2Live 5. Vladimir Danailov, CEO InvestSofia 6. Valentina Milanova, Founder and CEO, Daye 	<p><u>Keynote – Prof. Dr. Steffen Thirstrup, Director, NDA Regulatory Advisory Board, NDA Advisory Services Ltd.</u></p> <ol style="list-style-type: none"> 1. Bruce Magill, Director of Business Development, Personalised Medicine & Connected Health EMEA, SAP 2. Magda Chlebus, Executive Director, Science Policy and Regulatory Affairs, EFPIA 3. Andrew Fried, Business Development Director, Healthcare and Life Sciences Europe, IBM 4. Jordan Clark, Chief Commercial Officer, Diaceutics 	<p>oncology and chemotherapy. Not anymore, for sure.</p> <p><u>Keynote - Prof. Dr. Ron HN van Schaik, President European Society for Pharmacogenomics & Personalised Therapy (ESPT)</u></p> <ol style="list-style-type: none"> 1. Prof. Dr. Radka Argirova, Virologist, ACC Tokuda Hospital 2. Prof. Dr. Ivaylo Turnev, Head of Neurology Clinics, UMHAT Aleksandrovska – TBC 3. Prof. Radka Kaneva, Executive Manager Molecular Medicine Center, Medical University of Sofia 4. Dr. Marc Fackler, Business Development Manager, Life Codexx 5. Valentin Nikolov, SGP Biodynamics 	<p>other EU countries. We need to change this.</p> <p><u>Keynote - Prof. Michael Rossbach, Head of Technology Scouting, Eppendorf Group</u></p> <ol style="list-style-type: none"> 1. Charalampos-Philip Iosifidis, Managing Partner – Europe, Iota Omega Ventures Pte. Ltd. 2. Dr. Alexander Lezhava, Group leader - Translational Research 1, Genome Institute of Singapore (GIS), Agency for Science, Technology and Research (A*STAR) Program Director, POLARIS 3. Prof. Osman Ugur Sezerman, Head of Biostatistics and medical informatics Department, Acibadem Mehmet Ali Aydınlar Üniversitesi 4. Sergii Myronenko, Chairman, Kiev Clinical Research Forum
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15.00 – 16.00	<p>EATRIS – BAPEMED partnership. Can this cooperation change the landscape?</p> <p><u>Dr. Antonio Andreu, Scientific Director, EATRIS</u></p> <p><u>Dr. Stanimir Hasurdjiev, Chairman of the Administrative Board, BAPEMED</u></p>	<p>Clinical trials - Bulgaria is one of the best performers in clinical trials in Europe and even worldwide. Why and how to perform better?</p> <p><u>Keynote - Dr. Borislav Borissov, Managing Director, Prescriptia</u></p> <ol style="list-style-type: none"> 1. Dr. Sergii Myronenko, Chairman, Kiev Clinical Research Forum 2. Dr. Kamen Doxev, PSI Pharma Support 3. IQVIA representative – TBC 	<p>Biomarkers & Biobanking – Biomarkers are of paramount importance for personalized medicine. Biobanking might be the key for better biomarker development. Is this true?</p> <p><u>Keynote – Jordan Clark, Chief Commercial Officer, Diaceutics</u></p> <ol style="list-style-type: none"> 1. Prof. Radka Kaneva, Executive Manager Molecular Medicine Center, Medical University of Sofia 2. Dr. Alexander Lezhava, Group leader - Translational Research 1, Genome Institute of Singapore (GIS), Agency for Science, Technology and Research (A*STAR) Program Director, POLARIS 3. Dr. Kate Witkowska, Commercial Partnerships Manager, Genomics England 4. Prof. Michael Rossbach, Head of Technology Scouting, Eppendorf Group 	<p>How to keep young professionals in Bulgaria – PharmaLex. Brain drain is a big problem for Bulgaria. This is a consequence of several reasons and there will be panelists pro and con remaining in Bulgaria. A real HR expert will be the arbiter.</p> <p><u>Keynote – Georgi Kolev, Human Capital Director, Simbula</u></p> <ol style="list-style-type: none"> 1. Dr. Thomas Dobmeyer, CEO and Managing Partner, PharmaLex 2. Miglena Manova, Regulatory Affairs Manager, PharmaLex 3. Prof. Dr. Victoria Sarafian, Professor of Immunology, Department of Medical Biology, Medical University of Plovdiv 4. Valentina Milanova, Founder and CEO, Daye 5. Liliya Evtimova-Tichev, QA Validation Engineer, Lonza 6. Anna-Marie Vilamovska, Executive Director, Working Ideas
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16:00 – 16:30	Networking Coffee			
16.30 – 17.30	<p>How to establish scientific consortia and apply for EU funding - this is a hot topic in front of Horizon Europe. Bulgaria is criticized to be extremely passive, is this true?</p> <p><u>Keynote - TBD</u></p> <ol style="list-style-type: none"> 1. Prof. Osman Ugur Sezermann, Head of Biostatistics and medical informatics Department, Acibadem Mehmet Ali Aydınlar Üniversitesi 2. Prof. Dr. Victoria Sarafian, Professor of Immunology, Department of Medical Biology, Medical University of Plovdiv 3. Prof. Michael Rossbach, Head of Technology Scouting, Eppendorf Group 	<p>IT and Life Sciences - a lot of experts see the future of both ecosystem beyond a marriage. Is this the truth or is too early to dream?</p> <p><u>Keynote – Dr. Mads Dalsgaard</u>, Senior Vice President, Head of <u>Experimental Medicine & Clinical Development</u>, Lundbeck</p> <ol style="list-style-type: none"> 1. Rob Williams, Sr. Director, Regulatory Informatics and Digital Technologies, PharmaLex 2. Andrew Fried, Business Development Director, Healthcare and Life Sciences Europe, IBM 3. Bruce Magill, Director of Business Development, Personalised Medicine 	<p>Is Genomics Bulgaria/ Genomics Southeastern Europe possible? Genomic England achieved sensational results. Is this possible in other European regions?</p> <p><u>Keynote - Bogi Eliassen</u>, Associated Partner, Copenhagen Institute for Future Studies</p> <ol style="list-style-type: none"> 1. Paul Jones, Director, Population Genomics, Illumina 2. Dr. Kate Witkowska, Commercial Partnerships Manager, Genomics England 3. Prof. Radka Kaneva, Executive Manager Molecular Medicine Center, Medical University of Sofia 	<p>Patient advocacy groups in Life Sciences – yes, they are important, but their importance is taken into account. What is the state of art in the EU and in Bulgaria?</p> <p><u>Keynote - Dr. Stanimir Hasurdjiev</u>, Chairperson of <u>Bulgarian National Patients' Organization</u></p> <ol style="list-style-type: none"> 1. Piarella Peralta, Patient Advocate, Inspire2Live 2. Dr. Petja Stratieva, Chairperson of the Board, Retina Bulgaria, Development Executive Central & Eastern Europe, Retina International 3. Aneta Piperkova, COO, ProDuCt – PDC, Member of BAPEMED 4. Natalia Maeva, President, BSPPH - TBC

BIOTECH ATELIER

		& Connected Health EMEA, SAP		
17.30 – 18.30	<p>Could Life Sciences make 10% of the GDP in Bulgaria? <i>This is the key question, which we are seeking to answer</i></p> <ol style="list-style-type: none"> 1. Dr. Dimitar Georgiev, Founder and CEO Paralax Life Sciences 2. Evgeni Ivanov, General Manager, Euroconsultants Bulgaria S.A. AD 3. Kaloyan Staykov, Institute for Market Economics 			
18.30	Closing of Biotech Atelier 2.0			