小分子藥物開發產業聯盟/Dx-Hc 診斷照護醫材聯盟診斷照護醫材聯盟研討會

**講題**

**「精準醫療藥物與診斷開發商業策略實務解析」研討會**

1. Go-To-Market Strategies for Pharma-Diagnostics Companion Programs:

Activities and General Timing

1. Overcome Go-To-Market Hurdles and Case Studies

**Steven Rosen, Ph.D.**

Vice President, Business Development and Strategy

Elucida Oncology, Inc.

3. The Impact of the New Target or Clear™ Paradigm on Diagnostic and Therapeutic Precision Medicine Applications

**Edward L. Rosen**

President and Chief Executive Officer

Elucida Oncology, Inc.

3. The Landscape of Immuno-Oncology Development

**Jane SC Tsai, Ph.D., PMP, FAACC**

SVP International Affairs, YFY Biotech Management Company

Senior Adviser, ITRI

多元策略聯盟合作的產業價值鏈已是全球生技製藥與診斷等技術開發暨產業成長的發展趨勢，而近年來主導風雲的精準醫療與免疫療法更需要藥物與診斷廠商間的密切合作，原開發廠商透過策略聯盟、技術引進、或商業授權等方式，與其他廠商或組織合作，以提升效率、獲利空間及促進產品價值最大化。台灣產、學、研、醫界的創新研發成果與國際合作的機會日益頻繁，如何發掘潛在客戶，或當機會來敲門時，如何規劃您的商業模式、精進談判技巧，是個重要的議題！

本次演講由我們聯盟前會長，現任上騰生技顧問公司國際事務SVP及工研院生醫所資深特聘研究的蔡秀娟博士，特別邀請兩位經驗豐富的重量級講員進行實戰教學及經驗分享。

Dr. Steve Rosen歷任四家跨國大藥廠及一家新創公司，其在Johnson & Johnson的十四年間領導五案跨國策略聯盟及十案商業交易，創造每年三億美元的營收，另外並管理智慧財產策略及投資商機，爾後在Novartis Pharmaceuticals的Oncology BU領導諾華全球個人化醫療Phase I through III的新產品線及商業策略，並積極參與歐洲及美國精準醫療的主要組織，亦成功輔導多基因次世代基因定序的法規申請。

CEO Edward Rosen在創立Elucida Oncology, Inc.前在數家跨國醫材與藥廠領導創新、市場及給付策略，於Johnson & Johnson旗下帶領過手術醫材、心血管診療、癌症分子診斷及免疫等事業單位，包括重整免疫細胞治療事業體，兩年內由一億美金成長到四億，最後以十三億美金賣出。

本次內容涵蓋:進行跨國、跨同業或跨異業之精準醫療新藥與診斷合作開發上市策略規劃，包括國際藥廠間的合作模式、談判與規劃、全球各地市場差異的應對之道，藉由不同大廠間之策略夥伴如何解決困難的實例，來解析如何克服複雜藥物與診斷上市的層層障礙、以及免疫療法在藥物與診斷方面的現況與最新發展，期望透過與講師的交流了解其中的(眉角)關鍵技術，加速研發成果商品化。敬邀各位先進一起來研習與交流！

**主辦單位：**「小分子藥物開發產業聯盟」/「Dx-Hc 診斷照護醫材聯盟」/工研院生醫所

**時 間：**107年4月10日 (星期­二 9:00 am -13:00 pm)

**地 點：**集思台大會議中心 **米開朗基羅廳**(台北市羅斯福路四段85號地下一樓)

**報名費用：**「小分子藥物開發產業聯盟」會員、「Dx-Hc診斷照護醫材聯盟」會員、醫師、老師及學生免費。其他每位1,000元 (含講義與餐點)。

**議 程：**

|  |  |  |
| --- | --- | --- |
| 時間 | 題目 | 講師 |
| 09：00~09：20 |  |  |
| 09：20~09：30 | 致歡迎詞 | 黃崇雄、陳廷碩 |
| 09：30~10：10 | Go-To-Market Strategies for Pharma-Diagnostics Companion Programs: Activities and General Timing | **Steven Rosen, Ph.D.**  Vice President  Business Development and Strategy  Elucida Oncology, Inc. |
| 10：10~10 : 50 | Overcome Go-To-Market Hurdles and Case Studies |
| 10 : 50 ~11：10 | 休息時間 | |
| 11：10~ 11：50 | The Impact of the New Target or Clear™ Paradigm on Diagnostic and Therapeutic Precision Medicine Applications | **Edward L. Rosen**  President and Chief Executive Officer  Elucida Oncology, Inc.  New York |
| 11：50~12：15 | The Landscape of Immuno-Oncology Development | **Jane SC Tsai, Ph.D.**  SVP International Affairs, YFY Biotech Management Company |
| 12：15~12：30 | 綜合討論 | 上騰生技顧問公司  蔡秀娟博士 |
| 12：30~13：00 | 午餐 |  |

**報名方法:**

**「小分子藥物開發產業聯盟」會員**

**林舒蓉小姐 電話:03-5732850 信箱:** **lin0068@itri.org.tw**

**「Dx-Hc診斷照護醫材聯盟」會員**

**林瑋君小姐 電話:03-5918517 信箱:** **Twomilklin@itri.org.tw**

**繳費方式：**

□ 劃線即期支票 / 郵政匯票繳款：抬頭為「工業技術研究院」

請寄至：(300)新竹市光復路二段321號19館202室，林舒蓉小姐收，

電話:03-5732850

* 電匯繳款：銀行別：土地銀行工研院分行，帳號：156-005-00002-5，戶名：財團法人工業技術研究院，並於備註欄位說明「參加4/10「小分子藥物開發產業聯盟」或「診斷照護醫材聯盟」研討會」

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **公司名稱：** |  | | **統編** | |  | |
| **姓 名：** |  | **職 稱：** | |  | | **午餐** |
| **電 話：** |  | **E-mail：** | |  | | **葷🞏 素🞏** |

**本案聯絡人:**

**工研院生醫所 林慧琪小姐，電話:03-5743977 ， 信箱: huichilin@itri.org.tw**

**林舒蓉小姐，電話:03-5732850**

**講師簡歷:**

****

**Steven Rosen, Ph.D.**

**Vice President**

**Business Development and Strategy**

**Elucida Oncology, Inc.**

**New York**

Steve Rosen is the Vice President of Business Development and Strategy of Elucida Oncology,

Inc. Dr. Rosen has an excellent track record of maximizing the impact and success of

diagnostic and therapeutic assets.

Dr. Rosen has more than 30 years of operational and leadership experience in the life sciences

industry. Prior to Elucida, he was Executive Director, Pipeline and Commercial Strategy for

the Oncology Business Unit of Novartis Pharmaceuticals. In this role, he led a team

responsible for strategic direction for global personalized medicine commercial strategy for

Phase I through III compounds in the Novartis Oncology pipeline as well as supported

execution of personalized medicine programs for in-line brands. He was also the Novartis Cochair

on the Oncology Strategic Governance Group of the European Innovative Medicines

Initiative, the Novartis representative to the US Personalized Medicine Coalition and Co-

Chair of the Novartis translational Clinical Oncology/ Companion Diagnostics Committee

Prior to Novartis, Dr. Rosen enjoyed a 14 year career at Johnson & Johnson as a co-founder

of the Veridex circulating tumor cell-focused division and as a World-Wide Senior Director

of Business Development and Healthcare Investment for the Ortho Clinical Diagnostics

franchise. In this role, he oversaw 5 strategic business alliances that created over $300MM

per year in revenue and delivered 10 significant business transactions, driving overall business

growth. He also managed the company’s complex IP portfolio of thousands of patents and

managed a budget of $120MM that he applied to drive successful growth initiatives.

Earlier in his career, Dr. Rosen held a series of positions of increasing responsibility at Roche

and Becton Dickinson.

Dr. Rosen holds a B.A. in Biochemistry from Brandeis University, an M.S. and a Ph.D. from

New York University Medical School Sackler Institute of Biomedical Sciences and is a

graduate of the Technology Managers Development Program at the Kellogg Graduate School

of Management at Northwestern University.

**講師簡歷:**



**Edward L. Rosen**

**President and Chief Executive Officer**

**Elucida Oncology, Inc.**

**New York**

Ed Rosen is the founding CEO, President, Chief Executive Officer and a Director of Elucida Oncology, Inc. Mr. Rosen has a passion towards driving companies and the people within to fulfill their true potential. Over the last three years, he has created the licensing, infrastructure, strategy and team for Elucida Oncology to thrive.

Mr. Rosen has more than 20 years of operational and leadership experience in the life sciences industry. Prior to Elucida, he enjoyed a stellar career across a number of companies within Johnson & Johnson. As Worldwide Vice President of Marketing for a large surgical division, he developed an entirely new business model while overseeing the development of the leading direct to patient web presence in the industry. He co-led the re-birth of an immunology / oncology division setting it on a valuation journey from less than $100MM to $1.3Bn in five years. As Director of Health Economics and Reimbursement & Strategy for a large peripheral vascular division, Ed played an industry leading role in several national coverage determinations and developed a keen understanding of economic outcomes to add to his existing clinical trial design experience. As a marketer, he took a market-leading product suddenly and incorrectly facing an unheard of level of attack from competition, regulators and clinicians and doubled revenue from the previous #1 market share position. Prior to Johnson & Johnson, Ed started his career with Smith & Nephew, plc, with roles in the United Kingdom and United States, including marketing, operations, technology transfer and sales.

Mr. Rosen holds a Bachelor of Arts with Honors in Business from the University of Lincoln in the United Kingdom.

Other highlights include:

* J&J immuno-oncology company, Therakos (Value <$100MM when joined. Along with President, built it into a $400MM company in 2 years. 2 years after that, based on continued implementation of the same strategy by much of the same team we built, it sold for $1.3Bn.
* Owned and delivered the Therakos portfolio.
  + Led R&D, Operations, Clinical, Medical, Regulatory, QA, QC, Finance, Supply Chain and Marketing to define, develop, deliver, fix, maintain, transform.
  + Wins included rapidly establishing a new pharmaceutic manufacturing source, creating an entirely new multi-billion-dollar market for Crohn’s and eliminating FDA 483s observations from manufacturing audits.
* Created and ran the Latin American business.
  + Defined and built the commercial, clinical, pharmacovigilance, service, medical affairs and supply chain organization across 5 new markets and established a revenue foundation that has since thrived.
* Concurrent Management Board member and Commercial Lead for 2 J&J oncology companies.
  + Therakos, immuno-oncology therapeutic and Veridex, molecular diagnostic (circulating tumor cells).
  + Along with President, rebuilt both companies while showing comfort and capability with volume and complexity of deep daily involvement and leadership.
* Deep and long-standing experience in multi-stage clinical trial development and design
  + Across oncology, immunology and cardiovascular.
  + Company sponsored and NIH.
  + From Phase 0 through post-market studies
  + Incorporation of reimbursement needs in role as Director of Health Economics and Reimbursement Strategy for Cordis, then a J&J company.
* Leadership
  + Success in creating leadership teams from employee 1 on tight budgets to running large departments with large budgets.
  + Ed combines an intensity to deliver with a rewarding and enjoyable culture. His teams deliver. He attracts and retains the strongest of talent. He amplifies their professional growth and ensures everyone is always focused on the targets that matter.

**蔡秀娟Jane SC Tsai, Ph.D., PMP, FACB**

**上騰生技顧問公司 國際事務資深顧問**

**工研院生醫所 資深特聘研究**

Dr. Jane SC Tsai is currently SVP for International Affairs at YFY Biotech Management Company. She is also a Senior Advisor for Biomedical Technology and Device Research Laboratories (BDL) at Taiwan’s Industrial Technology Research Institute (ITRI), at which she served the roles of Deputy General Director and Chief Operating Officer until the end of 2016. She has led various cross-sector and cross-institutional biomedical R&D projects as well as Industrial Development projects in medical device and cosmetics. She actively provides advice to Industry-Academia partnership and alliances in both Medical Device and Drug Development.

After earning her B.S. degree from National Taiwan University and Ph.D. from the Pennsylvania State University, Dr. Tsai has over 30 years of postdoctoral achievements in biotechnology & biomedical research, development, and product strategic planning and commercialization. With her career spanning across hospital, academia, research institutes, consultancy, and industry, Dr. Tsai has collaborated with cross-sector partners globally. She conducted academic research in the areas of cell & microbiology, biologics, host immunity, and cancer research, including antibodies, cytokines, tumor progression, meta-analysis, immunotherapy and gene therapy. While serving for 16 years as an R&D Director and Research Leader at Roche Diagnostics, she led cross-functional, interdisciplinary, and transnational teams to achieve concept-to-commerce innovations, global product launches, key opinion leader networking, and total product lifecycle management. She directed broad R&D operations, ranging from special chemistry and antibody rare reagents to new technology assessments, and from assay development to instrument and system integration.

A leader in a spectrum of business planning and execution, Dr. Tsai also served on a variety of global strategic visioning processes and intellectual property committees. She participated in a number of international Regulatory Affairs and is a member of the Asian Harmonization Working Party (AHWP). She has expansive experience in knowledge and program management and has published and presented extensively in various platforms. Dr. Tsai is a Fellow of National Academy of Clinical Biochemistry (FACB) and is a long-term member of several leading biomedical and pharmaceutical organizations, including American Association for Cancer Research, American Association for Clinical Chemistry, American Association of Pharmaceutical Scientists, The International Association of Forensic Toxicologists, and more.