The A to Z of Global New Drug Development : Strategic Roadmap for Korea Biopharma

2022.**10.11**(화) 14:00~17:30
그랜드 인터컨티넨탈 서울 파르나스 국화홀(2F)

Time	Subject	Presenter
14:00~14:05	Welcome remarks	**Kevin Huh** (CEO, KIMCo)
14:05~14:10	Opening remarks	**Sora Lee** (VP, General Manager Korea, Syneos Health)
	Seminar Lecture	
14:10~14:25	Beginning with the end in mind: how do you find that diamond in the rough and take it through to market	**Ken Lee** (EVP, APAC General Manager, Syneos Health)
14:25~14:50	Now that you have your asset, how do you accelerate your development from POC	**Nicholas Kenny** (Chief Scientific Officer, Syneos Health)
14:50~15:10	Ensuring late phase / phase 3 success for your asset	**Stephanie Gonzalez** (SVP, Head of Biotech Solutions, Syneos Health) & **Suma Ramadas** (EVP, Medical Affairs, Syneos Health)
15:10~15:35	Building a value creating R&D function and partnership ecosystem that can deliver through to phase 3	**James Man** (Managing Director, R&D Advisory, Syneos Health) & **Stephanie Gonzalez** (SVP, Head of Biotech Solutions, Syneos Health)
15:35~15:55	The Biotech landscape - a crystal ball look to the future	**Nicholas Kenny** (Chief Scientific Officer, Syneos Health)
15:55~16:10	Coffee Break	
	Panel Discussion	
16:10~17:30	Panel Discussion (Including Q&A)	Chair: **Hanlim Moon** (CEO, MediRama) Panel: **Howard Lee** (Professor, SNU/SNUH) **Kihwan Park** (Professor, KAIST) **Syneos Health Speakers**

Seminar Lecture Agenda

Beginning with the end in mind: how do you find that diamond in the rough and take it through to market (Ken Lee)

Finding an optimal asset often begins with the end in mind. Understanding where we want to go from a geographical, disease area and market segment will provide a guiding light on the asset we select and the strategy to bring it to market.

Now that you have your asset, how do you accelerate your development from POC (Nicholas Kenny)

We'll examine the challenges of creating a harmonized global clinical development plan; engagement with regulatory authorities; impact of recent events (e.g. BREXIT). We will consider how to "Starting with the label in mind"; ensure development plans are focused on critical elements; where/when/types of evidence (clinical/medical, regulatory, HEOR) must be generated during development to meet stakeholder needs (payers, regulators, investors, clinicians, patients). Lastly, we will look at some examples of innovative study designs/regulatory pathways.

Ensuring late phase / phase 3 success for your asset (Stephanie Gonzalez & Suma Ramadas)

This discussion will provide guidance on regulatory consultation, planning, and key considerations for conducting Phase III trials, including operational logistics and KOL and site engagement strategies to ensure success.

Building a value creating R&D function and partnership ecosystem that can deliver through to phase 3 (James Man & Stephanie Gonzalez)

This topic will discuss key best practices for sponsors looking to drive their medicine assets through development. Discussion points include the 3 builds biotechs need (1. Maximising product value through aligned cross-functional strategy, 2. Organisational and functional capabilities build needed to execute product strategy, and 3. Enabling talent to innovate in an evolving organisation). The ideal timings for functional capabilities build, how to get the best from partners and RFP selection best practices will also be covered.

The Biotech landscape - a crystal ball look to the future (Nicholas Kenny)

In this session, we'll look at what we can learn from recent investment trends in the biotech sector, what these tell us about how investors look at to guide their decisions. From this we'll consider what worked/didn't - and perhaps why, and what this tells us about possible future trends. How are investors looking at novel markets (drugs and geographies) versus "better" drugs in existing settings, the impact of disease subtyping based on actionable molecular mutations, "grouping" of investments e.g. around rare disease portfolios, and ling vs short term strategies. What will be the expectations of your investors?


Ken Lee
Syneos Health


Nicholas Kenny
Syneos Health


Stephanie Gonzalez
Syneos Health


Suma Ramadas
Syneos Health


James Man
Syneos Health

Panel Discussion Agenda

"Challenges for the success of global new drug development by Korean biopharmaceutical companies"


Hanlim Moon
MediRama


Howard Lee
SNU/SNUH


Kihwan Park
KAIST

참석대상 제약바이오기업 신약개발 담당 부서 임원 (40인 내외)
참석방법 1) QR코드 스캔 → 참가신청서 작성 → 제출
2) https://forms.gle/BjweCqtn2nQywgaf9
등록기간 ~2022.09.30
등 록 비 무 료
문 의 KIMCo **신명배** 연구원(**02-6247-0916**, smb@kimc.or.kr)

KIMCo (재)한국혁신의약품컨소시엄 KOREA INNOVATIVE MEDICINES CONSORTIUM
Syneos Health