

**WORK SHOP ON  
DRUG DISCOVERY AND DEVELOPMENT –  
Concept, Clinic & Commercialization (D3C3)  
Module 2: Drug Development  
9<sup>th</sup> – 10<sup>th</sup> March 2018**

**PROGRAMME : 9<sup>th</sup> March 2018**

09:30 – 10:00 AM	Inauguration & Recap of Module 1	
<b>Time</b>	<b>Topic</b>	<b>Speaker</b>
10.00 – 10.30 AM	Clinical Trial Design: Basics	Dr. Julius Anthony Vaz Global Program Head, Novartis, Hyderabad
10.30 – 11.15 AM	Dose range finding studies: clinical development perspective	Dr. Ammar Raza Country Medical Director, Allergan
11.15 – 11.45 AM	High Tea	
11.45 – 12.45 PM	Phase 3a/3b registration clinical studies	Dr. Julius Anthony Vaz Global Program Head, Novartis, Hyderabad
12.45 – 14.00 PM	Lunch	
14.00 – 15.00 PM	Phase 4 and Real World Evidence (RWE) studies	Dr. Julius Anthony Vaz Global Program Head, Novartis, Hyderabad
15.00 – 16.00 PM	Pharmacovigilance – safety risk detection and management	Dr. Dhruvajyoti Pathak Brand Safety Leader, Global Drug Development, Novartis, Hyderabad
16.00 – 16.30 PM	High Tea	
16.30. – 17.30 PM	Clinical trial operations and data management	Ritesh Tiwari Novartis, Hyderabad
17.30 – 18.00 PM	Case study presentation	

**PROGRAMME : 10<sup>th</sup> March 2018**

09.30 – 10.15 AM	Regulatory considerations of Drug Development: Pharmaceutical and clinical development - Key aspects of USFDA and EMA	Dr Premnath Shenoy Former Director Regulatory and Patient Safety & Quality, AstraZeneca
10.15 – 11.15 AM	Quality and compliance in product development	Dr. Arani Chatterjee Aurobindo Pharma, Hyderabad
11.15 – 11.45 AM	High Tea	
11.45 – 12.45 PM	Statistical considerations – clinical development	Dr. Parasar Pal Novartis Hyderabad
12.45 – 14.00 PM	Lunch	
14.00 – 15.30 PM	Case study discussion	
15.30 – 16.00 PM	High Tea	
16.00 – 17.30 PM	Case study presentation	