

TUESDAY JULY 27 3:30pm zoom seminar

## The Road to the IND:

Efficiently De-risking Your Asset to Increase the Chances of Partnering

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Every year, around 3000 therapeutic patents are issued in the United States. Only a handful of these will ever make it to the clinic, while most will languish on the proverbial shelf, unable to attract capital. The challenge facing biomedical innovators then, is how to put together a package that de-risks their candidate molecule to the point where investors and strategic partners are willing to take the leap of faith. In this context, the Investigational New Drug (IND) application will be the first hurdle that a partnered asset will face, so structuring the data package to address questions that must be addressed in the IND provides your asset with an advantage. Many of these questions are around clinical trial design- what is the right dose? what is the right schedule? who are the right patients? While it's easy enough to answer these questions (pick a number!), a rigorous IND-supporting package contains answers to these questions based on a careful integration of biology with preclinical (and where relevant) clinical pharmacology. In this seminar, we will show you how to address these questions using the techniques of Model-Based Drug Development, allowing you to speak to potential Big Pharma partners in their language.



**Arijit Shakravarty** has served as the CEO of Fractal Therapeutics since its inception in 2016. Fractal Therapeutics engages with partners to move assets efficiently to clinical proof-of-concept using model-based drug development approaches while also advancing its own preclinical assets. Prior to his time at Fractal, Arijit spent 12 years in Takeda Pharmaceuticals, in roles of increasing responsibility in in vivo Pharmacology, Translational Research, Computational Biology and DMPK. Over this period, he contributed to over 50 drug development programs, served as a discovery Project Team Leader for 7 late-preclinical and early-clinical programs, and played a pivotal role in numerous IND filings.

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