



CSI FOCUS WORKSHOP:

DEVICE DEVELOPMENT

JUNE 26, 2019 IN FRANKFURT, GERMANY

Workshop coordinator: Sameer Gafoor

10:30 – 12:30 **Preclinical: From prototype to product and associated funding challenges**

Moderators: Todd Brinton, Sameer Gafoor

World full of changes – what are they? / Yuval Binur

Patents and pitfalls / Maarten Ketelaars

Animal models: Selection and limitations / Alope Virmani Finn

Validation and verification: Structure & design / Richard Lilly

Expectation alignment in the pre-clinical process: Entrepreneurs and investors

- Interview by Stephen Levin / Nicolas Borenstein, Stanley Rabinovich

Case example CardiacBooster / Daniel van Dort

Panel discussion

12:30-13:30 **Lunch boxes and networking,
poster presentations**

13:30-15:15 **Clinical: From animals to humans and associated funding challenges**

Moderators: Sameer Gafoor, Kathleen Marshall

Evolving regulatory landscapes—Europe / Volker Lücker

Evolving regulatory landscapes & protocol development—USA / Sujith Shetty

Evolving regulatory landscapes—alternative options to US and Europe / Carlos Granada

Expectation alignment in the clinical process: Entrepreneurs and investors

- Interview by David Cassak / Charles Taylor, Hanson Gifford, Ted Feldman

Case example AMT Medical / Rutger Tulleken
Case example AutoTissue Berlin / Christoph Schmitz

Panel discussion

15:15-15:45 Coffee break

15:45-18:00 Commercialization: From clinical research to reality and associated funding challenges

Moderators: Todd Brinton, Stanley Rabinovich

Clinical trial execution: Meeting the milestones and managing resources / Kathleen Marshall
Reimbursement: Managing the process / Mattias Kyhlstedt
Collecting Data and Generating Insights during Clinical Research / Barbara Zwick
Learning from Failures / Yuval Binur

Expectation alignment in the post-market process: Investors and entrepreneurs
- Interview by Stephen Levin and David Cassak / Jeff Jump, Florian Ludwig

Case example EchoPixel / Sergio Aguirre
Case example Thermopeutix / Ron Solar

Panel discussion

18:05-18:15 Closing remarks

This workshop is part of CSI Frankfurt, the leading conference on congenital, structural and valvar heart disease interventions, which will take place June 26-29, 2019 in Frankfurt, Germany.

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Please note the program is still in development and subject to change.