

# SESSIONS

DAY ONE - 07/03/2022

## Decentralized Clinical Trials

Delivered as a Hybrid Event, March 7 - 9, 2022

Live In-Person Event: March 7-9, Hyatt Regency Coral Gables, Miami, Florida

Digital Experience: Live-streamed keynotes only on March 7-9, plus all presentation recordings on-demand from March 14th

### Registration

11:00am - 12:00pm

### Lunch and Exhibition Hall Opens

12:00pm - 12:55pm

### Conference Opening Remarks and Welcome

12:55pm - 1:00pm

INDUSTRY CASE STUDIES & LESSONS LEARNT

### KEYNOTE: Forecasts for the Future of Decentralized and Digital Clinical Trials

1:00pm - 1:30pm

INDUSTRY CASE STUDIES & LESSONS LEARNT

- Explore the evolution of roles resulting in DCT adoption
- Consider events that will impact adoption curves over the next five years
- Discuss potential futures beyond the adoption of today's DCT models

### Participants

**Craig Lipset** - Founder & Advisor, Clinical Innovation Partners, USA, Co-Chair, Decentralized Trials & Research Alliance (DTRA), USA

### KEYNOTE Spotlight Presentation: Care Access

1:30pm - 2:00pm

INDUSTRY CASE STUDIES & LESSONS LEARNT

### CASE STUDY: Operationalization of DCT Trials

2:00pm - 2:30pm

INDUSTRY CASE STUDIES & LESSONS LEARNT

### Participants

**Shelly Barnes** - Innovation Lead, Global Clinical Sciences and Operations, UCB, USA

### Spotlight Presentation: The Past, Present and Future Trends on Decentralized Clinical Trials Enabled by Digital Health Technologies

2:30pm - 3:00pm

INDUSTRY CASE STUDIES & LESSONS LEARNT

This talk will cover lessons learned and use cases for the following topics:

- Past: episodic uptake of DCTs with sudden catalysis by COVID-19
- Present: current adoption of DCTs and areas of research
- Future: trends on DCTs with emphasis on integration due to technological advances

### Participants

**Isaac Rodriguez-Chavez, PhD, MHSc, MSc** - Senior Vice President, Scientific & Clinical Affairs, Global Center of Excellence for Decentralized Clinical Trials, PRA Health Sciences

### CASE STUDY: Current Challenges for DCTs Experienced by Sponsors in Germany

3:00pm - 3:30pm

INDUSTRY CASE STUDIES & LESSONS LEARNT

- What are the different challenges in Germany?
- Broad overview of what to expect with Medicine agency and ethics committees
- Collective results from surveys from pharmaceutical industry in Germany
- European discussion on DCTs

### Participants

**Thorsten Ruppert** - Senior Manager, Research/Development/Innovation, Vfa, Research-Based Pharmaceutical Companies, Germany

### Afternoon Coffee Break and Networking

3:30pm - 4:00pm

INDUSTRY CASE STUDIES & LESSONS LEARNT

### Spotlight Presentation: Castor EDC

4:00pm - 4:30pm

INDUSTRY CASE STUDIES & LESSONS LEARNT

### CASE STUDY: How Lundbeck Have Developed an Internal Ecosystem Around DCT and are Running Pilot Studies

4:30pm - 5:00pm

INDUSTRY CASE STUDIES & LESSONS LEARNT

### Participants

**Jennifer Logue Nielsen** - Senior Specialist, Clinical Data Management, H. Lundbeck A/S, Denmark

### Spotlight Presentation: Medocity

5:00pm - 5:30pm

INDUSTRY CASE STUDIES & LESSONS LEARNT

### TransCelerate's Modernize Clinical Trials Conduct

5:30pm - 6:00pm

INDUSTRY CASE STUDIES & LESSONS LEARNT

### Participants

**Joachim Lövin** - eTrials Senior System Supporter, Novo Nordisk, Denmark

### End of Day One

6:00pm - 6:05pm

INDUSTRY CASE STUDIES & LESSONS LEARNT

Please contact: **Nick Matthews**  
[nicholas.matthews@informa.com](mailto:nicholas.matthews@informa.com)

**+44 (0)20 337 73905** if you are interested in Sponsoring the Drinks Reception

# SCHEDULE

DAY ONE - 07/03/2022

Decentralized Clinical Trials

Delivered as a Hybrid Event, March 7 - 9, 2022

Live In-Person Event: March 7-9, Hyatt Regency Coral Gables, Miami, Florida

Digital Experience: Live-streamed keynotes only on March 7-9, plus all presentation recordings on-demand from March 14th

TIME	INDUSTRY CASE STUDIES & LESSONS LEARNT
11:00AM	11:00am - Registration
12:00PM	12:00pm - Lunch and Exhibition Hall Opens 12:55pm - Conference Opening Remarks and Welcome
1:00PM	1:00pm - KEYNOTE: Forecasts for the Future of Decentralized and Digital Clinical Trials 1:30pm - KEYNOTE Spotlight Presentation: Care Access
2:00PM	2:00pm - CASE STUDY: Operationalization of DCT Trials 2:30pm - Spotlight Presentation: The Past, Present and Future Trends on Decentralized Clinical Trials Enabled by Digital Health Technologies
3:00PM	3:00pm - CASE STUDY: Current Challenges for DCTs Experienced by Sponsors in Germany 3:30pm - Afternoon Coffee Break and Networking
4:00PM	4:00pm - Spotlight Presentation: Castor EDC 4:30pm - CASE STUDY: How Lundbeck Have Developed an Internal Ecosystem Around DCT and are Running Pilot Studies
5:00PM	5:00pm - Spotlight Presentation: Medocity 5:30pm - TransCelerate's Modernize Clinical Trials Conduct
6:00PM	6:00pm - End of Day One

# SESSIONS

DAY TWO - 08/03/2022

## Decentralized Clinical Trials

Delivered as a Hybrid Event, March 7 - 9, 2022

Live In-Person Event: March 7-9, Hyatt Regency Coral Gables, Miami, Florida

Digital Experience: Live-streamed keynotes only on March 7-9, plus all presentation recordings on-demand from March 14th

### Morning Coffee

8:00am - 8:30am

### CASE STUDY: A Fully Decentralized Trial Running at LEO Pharma

8:30am - 9:00am

INDUSTRY CASE STUDIES & OPERATIONAL CHALLENGES

- LEOs approach of enabling technologies in clinical trials
- Study: The aim is for the majority of patients to participate without any on-sites visits (fully decentralized)
- To share knowledge and learnings from our interactions with the authorities
- Future aspirations and roadmap

### Participants

**Mads Bo Christensen** - R&D Project Manager, LEO Pharma A/S, Denmark

**Thomas Coquelle** - Principal Clinical Project Manager in Revolutionize Clinical Trials, LEO Pharma A/S, Denmark

### KEYNOTE Spotlight Presentation: IQVIA

9:00am - 9:30am

INDUSTRY CASE STUDIES & OPERATIONAL CHALLENGES

### CASE STUDY: ALPHA-T - "A First" Fully Decentralized Trial in Oncology

9:30am - 10:00am

INDUSTRY CASE STUDIES & OPERATIONAL CHALLENGES

### Participants

**Elizabeth Theogaraj** - Global Regulatory Lead, Roche

### Spotlight Presentation: Available

10:00am - 10:30am

INDUSTRY CASE STUDIES & OPERATIONAL CHALLENGES

Please contact: Nick Matthews  
nicholas.matthews@informa.com

+44 (0)20 337 73905 if you are interested in participating as a speaker, panellist, moderator or hosting a webinar

### CASE STUDY: How Decentralized Trials has been Adopted Within AstraZeneca

10:30am - 11:00am

INDUSTRY CASE STUDIES & OPERATIONAL CHALLENGES

- Practical application and guidance
- RQA - Research Quality Assurance

### Participants

**Fatemeh Jami** - Director, Strategic Advice, AstraZeneca R&D Quality Assurance, UK

### Morning Coffee Break and Networking

11:00am - 11:30am

INDUSTRY CASE STUDIES & OPERATIONAL CHALLENGES

### Spotlight Presentation: THREAD

11:30am - 12:00pm

INDUSTRY CASE STUDIES & OPERATIONAL CHALLENGES

### How Digital is "Schooling" Pharma and Challenging Assumptions about Participation in Decentralized Clinical Trials

12:00pm - 12:30pm

INDUSTRY CASE STUDIES & OPERATIONAL CHALLENGES

- The pandemic exposed long-standing issues with access to high-quality care and overall well-being.
- Why is an ecosystem approach necessary to accelerate outcomes and impact?
- How do patients describe "patient-centered"?
- Strategic collaborative partnering
- What is the right mix of traditional and non-traditional partners (who are trusted by patients)?
- Are there potential partners absent who already apply best practices?
- Competitive advantage
- In what ways can we leverage digital tools to meet patients where they are and enhance patient and site experience?

### Participants

**Kendal Whitlock** - Metasite Strategic Engagement Lead, Clinical Development & Operations Corporate, Boehringer Ingelheim GmbH & Co KG, Germany, Boehringer Ingelheim GmbH & Co KG, USA

### Spotlight Presentation: DCT Triumphs and Travails: Revelations from the First Fully Virtual Study Conducted in the Uro-gyno Category

12:30pm - 1:00pm

INDUSTRY CASE STUDIES & OPERATIONAL CHALLENGES

Just when COVID began to wreak havoc on research, Renovia, an innovative digital therapeutics company dedicated to improving women's Pelvic Floor Health, sought to conduct a trial to evaluate the efficacy of an at-home pelvic digital health system (PDHS) benchmarked against the current standard of care. The study team had plenty of concerns about going virtual: Would older women see technology as a barrier to participation? Could they be enrolled and trained remotely and would they understand their responsibilities? Would they be able to virtually recruit enough participants to power the study and could they keep them engaged throughout without face to face contact? Ultimately they decided to take the risk and partner with DCT expert ObvioHealth to run a fully decentralized trial. While things went (mostly) right, there was plenty to learn. Listen to Robin Sutherland and Matty Culbreth Notaro share insights on the fruits of their collaboration and take away lessons on how to embrace DCT methods while avoiding missteps.

### Participants

**Matty Notaro** - Chief Operating Officer, Obvio Health, USA

**Robin Sutherland** - Vice President of Human Resources and Clinical Operations, Renovia, USA

### Lunch and Networking

1:00pm - 2:00pm

INDUSTRY CASE STUDIES & OPERATIONAL CHALLENGES

### Spotlight Presentation: Care Access

2:00pm - 2:30pm

INDUSTRY CASE STUDIES & OPERATIONAL CHALLENGES

### CASE STUDY: Talk Title TBC

2:30pm - 3:00pm

INDUSTRY CASE STUDIES & OPERATIONAL CHALLENGES

### Participants

**Arturo Loiza-Bonilla** - Enterprise Director of Research, Cancer Treatment Centers of America, USA

# SESSIONS

DAY TWO - 08/03/2022

Decentralized Clinical Trials

Delivered as a Hybrid Event, March 7 - 9, 2022

Live In-Person Event: March 7-9, Hyatt Regency Coral Gables, Miami, Florida

Digital Experience: Live-streamed keynotes only on March 7-9, plus all presentation recordings on-demand from March 14th

---

## Spotlight Presentation: mdgroup

3:00pm - 3:30pm

INDUSTRY CASE STUDIES & OPERATIONAL CHALLENGES

### Participants

**Caroline Jackson** - EVP, Patient Services, MD Group, UK

---

## PANEL: Decentralized Trials – Solves Problems but Creates New Ones?

3:30pm - 4:15pm

INDUSTRY CASE STUDIES & OPERATIONAL CHALLENGES

- DCTs create more inclusion and diversity
- How to standardise all diagnostic and outcome testing
- How is data collection equivalent when it is being done in a non-medical setting?
- What are the operational challenges to DCT?
- What problems does it solve? But what problems does it create? What are the solutions to these new problems?
- Systems modelling for comparing and contrasting traditional clinical trials to decentralized clinical trials?

### Participants

**Ivan Gonzalez** - Medical Doctor Investigator, UMO, USA

**Thorsten Ruppert** - Senior Manager, Research/Development/Innovation, Vfa, Research-Based Pharmaceutical Companies, Germany

**Mads Bo Christensen** - R&D Project Manager, LEO Pharma A/S, Denmark

---

## Afternoon Coffee Break and Networking

4:15pm - 4:45pm

INDUSTRY CASE STUDIES & OPERATIONAL CHALLENGES

---

## Spotlight Presentation: Clario

4:45pm - 5:15pm

INDUSTRY CASE STUDIES & OPERATIONAL CHALLENGES

---

## Five Years' Experience of Managing a Hybrid Clinical Trials on Complex Oncology Studies

5:15pm - 5:45pm

INDUSTRY CASE STUDIES & OPERATIONAL CHALLENGES

- 5 years' experience running a hybrid DCT
- Benefits for site and patient
- How to do it with smaller early phase studies

### Participants

**Len Rosenberg** - Head, Clinical Operations, Beat AML, a division of The Leukemia and Lymphoma Society, USA

---

## Drinks Reception

5:45pm - 6:45pm

INDUSTRY CASE STUDIES & OPERATIONAL CHALLENGES

Please contact: Nick Matthews  
[nicholas.matthews@informa.com](mailto:nicholas.matthews@informa.com)

**+44 (0)20 337 73905** if you are interested in Sponsoring the Drinks Reception

# SCHEDULE

DAY TWO - 08/03/2022

Decentralized Clinical Trials

Delivered as a Hybrid Event, March 7 - 9, 2022

Live In-Person Event: March 7-9, Hyatt Regency Coral Gables, Miami, Florida

Digital Experience: Live-streamed keynotes only on March 7-9, plus all presentation recordings on-demand from March 14th

TIME	INDUSTRY CASE STUDIES & OPERATIONAL CHALLENGES
<b>8:00AM</b>	<b>8:00am</b> - Morning Coffee <b>8:30am</b> - CASE STUDY: A Fully Decentralized Trial Running at LEO Pharma
<b>9:00AM</b>	<b>9:00am</b> - KEYNOTE Spotlight Presentation: IQVIA <b>9:30am</b> - CASE STUDY: ALPHA-T - "A First" Fully Decentralized Trial in Oncology
<b>10:00AM</b>	<b>10:00am</b> - Spotlight Presentation: Available <b>10:30am</b> - CASE STUDY: How Decentralized Trials has been Adopted Within AstraZeneca
<b>11:00AM</b>	<b>11:00am</b> - Morning Coffee Break and Networking <b>11:30am</b> - Spotlight Presentation: THREAD
<b>12:00PM</b>	<b>12:00pm</b> - How Digital is "Schooling" Pharma and Challenging Assumptions about Participation in Decentralized Clinical Trials <b>12:30pm</b> - Spotlight Presentation: DCT Triumphs and Travails: Revelations from the First Fully Virtual Study Conducted in the Urogyno Category
<b>1:00PM</b>	<b>1:00pm</b> - Lunch and Networking
<b>2:00PM</b>	<b>2:00pm</b> - Spotlight Presentation: Care Access <b>2:30pm</b> - CASE STUDY: Talk Title TBC
<b>3:00PM</b>	<b>3:00pm</b> - Spotlight Presentation: mdgroup <b>3:30pm</b> - PANEL: Decentralized Trials – Solves Problems but Creates New Ones?
<b>4:00PM</b>	<b>4:15pm</b> - Afternoon Coffee Break and Networking <b>4:45pm</b> - Spotlight Presentation: Clario
<b>5:00PM</b>	<b>5:15pm</b> - Five Years' Experience of Managing a Hybrid Clinical Trials on Complex Oncology Studies <b>5:45pm</b> - Drinks Reception

# SESSIONS

DAY THREE - 09/03/2022

## Decentralized Clinical Trials

Delivered as a Hybrid Event, March 7 - 9, 2022

Live In-Person Event: March 7-9, Hyatt Regency Coral Gables, Miami, Florida  
Digital Experience: Live-streamed keynotes only on March 7-9, plus all presentation recordings on-demand from March 14th

### Morning Coffee

8:00am - 8:30am

### Engaging Patients in Decentralized Clinical Trials: Best Practices

8:30am - 9:00am

OPERATIONAL CHALLENGES, TECHNOLOGY & INNOVATION

#### Participants

**Ricki Fairley** - Chief Executive Officer, TOUCH, The Black Breast Cancer Alliance, USA

### KEYNOTE Spotlight Presentation: Available

9:00am - 9:30am

OPERATIONAL CHALLENGES, TECHNOLOGY & INNOVATION

Please contact: Nick

Matthews [nicholas.matthews@informa.com](mailto:nicholas.matthews@informa.com)

+44 (0)20 337 73905 if you are interested in participating as a speaker, panellist, moderator or hosting a webinar

### Decentralized Trials: The Challenges with New Technologies

9:30am - 10:00am

OPERATIONAL CHALLENGES, TECHNOLOGY & INNOVATION

- Managing new way to communicate
- Managing new tools and platforms
- How to recruit patients through a pandemic
- The importance of keeping the Technology updated

#### Participants

**Ivan Gonzalez** - Medical Doctor Investigator, UMO, USA

### Spotlight Presentation: Available

10:00am - 10:30am

OPERATIONAL CHALLENGES, TECHNOLOGY & INNOVATION

Please contact: Nick Matthews

[nicholas.matthews@informa.com](mailto:nicholas.matthews@informa.com)

+44 (0)20 337 73905 if you are interested in participating as a speaker, panellist, moderator or hosting a webinar

### What are the Diversity Opportunities and how can Decentralized Trials be promoted in Clinical Trials and Recruitment?

10:30am - 11:00am

OPERATIONAL CHALLENGES, TECHNOLOGY & INNOVATION

- Decentralized trials will improve recruitment plus a bigger pool of patients will increase diversity.
- Socioeconomic cultural and genetic populations that have never been exposed to trials- bad for research as doesn't have the wealth of data from these populations.

#### Participants

**Maimah Karmo** - Patient Advocate and CEO, Tigerlily Foundation, USA

### Morning Coffee and Networking

11:00am - 11:30am

OPERATIONAL CHALLENGES, TECHNOLOGY & INNOVATION

### Spotlight Presentation: UBC

11:30am - 12:00pm

OPERATIONAL CHALLENGES, TECHNOLOGY & INNOVATION

#### Participants

**Ned Hull** - Marketing Coordinator, UBC, USA

### The Role of Digital Technologies in Advancing D&I in Clinical Trials

12:00pm - 12:30pm

OPERATIONAL CHALLENGES, TECHNOLOGY & INNOVATION

- How adoption of new practises and metrics measures can move the dial
- The role of digital technologies in different settings (site, remote)

#### Participants

**Adama Ibrahim** - Digital Solutions Director, Novartis, Switzerland

**Kim Fookes** - Global Head, Diversity and Inclusion in Clinical Trials, Novartis, USA

### PANEL: Diversity and Inclusion in Clinical Trials

12:30pm - 1:15pm

OPERATIONAL CHALLENGES, TECHNOLOGY & INNOVATION

#### Participants

**Adama Ibrahim** - Digital Solutions Director, Novartis, Switzerland

**Kim Fookes** - Global Head, Diversity and Inclusion in Clinical Trials, Novartis, USA

**Ricki Fairley** - Chief Executive Officer, TOUCH, The Black Breast Cancer Alliance, USA

### Lunch and Networking

1:15pm - 2:15pm

OPERATIONAL CHALLENGES, TECHNOLOGY & INNOVATION

### Spotlight Presentation: To Decentralize or not to Decentralize, that is the Question

2:15pm - 2:45pm

OPERATIONAL CHALLENGES, TECHNOLOGY & INNOVATION

What does it mean to decentralize? Designing a study with decentralized visits in mind:

- Lessons learned from mid-pandemic implementation
- Procedures that fit the decentralized visit model
- Considering the site and patient perspective

#### Participants

**Shelby Stillwagon** - Senior Director, Decentralized Clinical Trials, ProPharma Group, USA

### Adaptive Clinical Trial Design

2:45pm - 3:15pm

OPERATIONAL CHALLENGES, TECHNOLOGY & INNOVATION

#### Participants

**Ankeet Bhatt** - Brigham and Women's Hospital, Harvard Medical School, USA

---

### Spotlight Presentation: Successes and Learnings taken from a Site-less and Fully Decentralized Phase 2 COVID-19 Clinical Trial in the UK Outpatient Setting

3:15pm - 3:45pm

OPERATIONAL CHALLENGES, TECHNOLOGY & INNOVATION

- In 2021, Bionical Emas delivered a Phase 2 COVID clinical trial in the UK in patients with asymptomatic or mild COVID-19.
- UK legislation states that this patient population must quarantine at home for 10 days after a positive COVID-19 test, and therefore a traditional site based model was not appropriate.
- A site-less and fully decentralised study design was implemented, where all visits took place virtually or through visits to the participants home (or other location convenient to them), including shipment of the investigational medicinal product and blood/PCR samples.
- This presentation will:
  - describe the study design;
  - review the operational challenges that were overcome, and learnings to take forward into future studies;
  - celebrate successes for the study, which included positive recruitment and retention rates.

#### Participants

**Helen Kirkby** - Director Account Management, DTRA Leadership Council Representative, Bionical Emas, UK

---

### Afternoon Coffee Break and Networking

3:45pm - 4:15pm

OPERATIONAL CHALLENGES, TECHNOLOGY & INNOVATION

---

### Spotlight Presentation: Available

4:15pm - 4:45pm

OPERATIONAL CHALLENGES, TECHNOLOGY & INNOVATION

Please contact: **Nick Matthews**  
[nicholas.matthews@informa.com](mailto:nicholas.matthews@informa.com)

**+44 (0)20 337 73905** if you are interested in participating as a speaker, panellist, moderator or hosting a webinar

---

### Simplifying Protocols for DCT-Friendly Trials

4:45pm - 5:15pm

OPERATIONAL CHALLENGES, TECHNOLOGY & INNOVATION

- The history of DCTs
- How complexity can kill DCTs
- How to simplify trials
- Example: the TOPAZ trial

#### Participants

**Steven Cummings** - Director, Professor of Medicine, Epidemiology and Biostatistics, University of California, San Francisco, USA

---

### Analytical Applications of Implications of DCT Data

5:15pm - 5:45pm

OPERATIONAL CHALLENGES, TECHNOLOGY & INNOVATION

- Different algorithms and analyses to utilise to use for DCT focused data
- The utility of wearables for DCT
- What complimentary information can wearable device data provide us as compared to traditional clinical trial data

#### Participants

**Vanja Vljajnic** - Sr. Manager, Statistics and Data Insights, Bayer Science Fellow, Bayer U.S. LLC

---

### End of Conference

5:45pm - 5:50pm

# SCHEDULE

DAY THREE - 09/03/2022

Decentralized Clinical Trials

Delivered as a Hybrid Event, March 7 - 9, 2022

Live In-Person Event: March 7-9, Hyatt Regency Coral Gables, Miami, Florida

Digital Experience: Live-streamed keynotes only on March 7-9, plus all presentation recordings on-demand from March 14th

TIME	OPERATIONAL CHALLENGES, TECHNOLOGY & INNOVATION
<b>8:00AM</b>	<b>8:00am</b> - Morning Coffee <b>8:30am</b> - Engaging Patients in Decentralized Clinical Trials: Best Practices
<b>9:00AM</b>	<b>9:00am</b> - KEYNOTE Spotlight Presentation: Available <b>9:30am</b> - Decentralized Trials: The Challenges with New Technologies
<b>10:00AM</b>	<b>10:00am</b> - Spotlight Presentation: Available <b>10:30am</b> - What are the Diversity Opportunities and how can Decentralized Trials be promoted in Clinical Trials and Recruitment?
<b>11:00AM</b>	<b>11:00am</b> - Morning Coffee and Networking <b>11:30am</b> - Spotlight Presentation: UBC
<b>12:00PM</b>	<b>12:00pm</b> - The Role of Digital Technologies in Advancing D&I in Clinical Trials <b>12:30pm</b> - PANEL: Diversity and Inclusion in Clinical Trials
<b>1:00PM</b>	<b>1:15pm</b> - Lunch and Networking
<b>2:00PM</b>	<b>2:15pm</b> - Spotlight Presentation: To Decentralize or not to Decentralize, that is the Question <b>2:45pm</b> - Adaptive Clinical Trial Design
<b>3:00PM</b>	<b>3:15pm</b> - Spotlight Presentation: Successes and Learnings taken from a Site-less and Fully Decentralized Phase 2 COVID-19 Clinical Trial in the UK Outpatient Setting <b>3:45pm</b> - Afternoon Coffee Break and Networking
<b>4:00PM</b>	<b>4:15pm</b> - Spotlight Presentation: Available <b>4:45pm</b> - Simplifying Protocols for DCT-Friendly Trials
<b>5:00PM</b>	<b>5:15pm</b> - Analytical Applications of Implications of DCT Data <b>5:45pm</b> - End of Conference