CRITICAL PATH INSTITUTE

April 18 – 20 | 2023 CDRC Annual Meeting

C-Path's Cure Drug Repurposing Collaboratory will host an in-person, three-day annual Conference and Regulatory Workshop on April 18-20, 2023, at the Hyatt Regency Crystal City in Arlington, Virginia. Together with key stakeholder groups including clinicians, researchers, foundations, nonprofits, patient advocates and regulators, CDRC will host a series of talks and roundtable discussions to share recent accomplishments.

This conference will better define how CDRC can best collaborate to capture real-world data to generate hypothesis regarding treatment efficacy using repurposed drugs for diseases of high unmet clinical need and where there is a lack of commercial incentives. The meeting will include key opinion leaders from numerous disease communities, experts on automated EHR data extraction, regulators from the global community, and partnerships to inform and champion large adaptive platform trials.

Speaker / Panelists Bios
View the presentations from Day One here
View the presentations from Day Two here
View the presentations from Day Three here.
View the detailed agenda here.

Agenda

April 18	**<u>CDRC Regulatory Workshop Day 1: Tuesday, April 18</u>**
	
	International workshop for publicly funded repurposing programs focusing o
	which do not have a commercial sponsor.
	
	• Regulatory Drug Repurposing Workshop
	  ○ Introduction: Rosie Lovett | 8:30-8:45
	• **Cochairs: Marco Schito & John Liddicoat**
	• 8 Speakers (5 min lightning talks)| 8:45 – 10:30
	  ○ Rosie Lovett (NHS) | 8:45– 8:50
	  ○ Heather Stone (FDA) | 8:50 – 8:55
	  ○ Sundeep Agrawal (FDA) | 8:55–9:00
	  ○ Pedrita Taylor Zapada (NICHD) | 9:00-9:05
	  ○ Sabine Grimm (REPO4EU) 9:05 – 9:10
	  ○ Donald Lo (REMIDi4ALL) | 9:10–9:15
	  ○ Charlotte Asker-Hagelberg (Sweden – MPA) | 9:15–9:20
	  ○ Questions/Answers | 9:20-10:00
	
	Break
	
	• **Cochairs: Rosie Lovett & Donald Lo**
	  ○ Panel 1: Candidate Identification | 10:30-12:00
	  ○ Sundeep Agrawal
	  ○ Sabine Grimm
	  ○ Charlotte Asker-Hagelberg
	  ○ Marjon Pasmooij
	  ○ Perdita Taylor-Zapata
	
	Lunch | 12:00-1:00
	
	• Unleashing the Potential of Financial Orphans: Blueprint for a Nationa
	  Vikas Sukhatme (Emory Morningside Center for Innovative and Affor
	  Medicine) | 1:00 – 1:30
	  ○ ?aneta Zem?a-Pacud (Polish Academy of Sciences) | 1:30 – 2:00
	  ○ James Robinson (UC Berkeley) 2:00-2:30
	  ○ Using Interventional Pharmacoeconomics and Advance Market
	  to Repurpose Generic Drugs with Cost Savings – Savva Kerdem
	  Funded Cures) | 2:00-2:20
	
	Break | 2:30-3:00
	
	Moderators: Marco Schito and David Simon
	
	• Panel 2: RCTs, licensing, trial funding? 3:00 – 4:30
	  ○ Patricia Van damme (Anticancer fund)
	  ○ Amit Aggarwal (ABPI)
	  ○ James Robinson (UCB)
	  ○ ?aneta Zem?a-Pacud (Polish Academy of Sciences)
	  ○ Clare Thibodeaux (Cures within Reach)
	  ○ Vikas Sukhatme (Morningside)
	  ○ Cynthia Adinig (Patient)
	
	Next steps (close of open session) | 4:30-45
	
	• **Cochairs: Rosie Lovett and Heather Stone**
	  ○ Closed session with publicly funded programs| 4:45-5:300

April 19 AM	**<u>CDRC Annual Meeting Day 2: Wednesday, April 19</u>** **Join via Zoom Meeting: https://c-path-org.zoom.us/j/96887365766?pwd=YkpYUU1XWVpqb1BzZ3hSaFFyQnh** ○ **Meeting ID: 968 8736 5766** ○ **Passcode: 900436** *Development of open-sourced tools to automate the collection of repurposed electronic medical records to generate real-world data.* **Morning: Meeting kickoff on automating data extraction from EHRs** • Welcome and Overview:: Marco Schito (C-Path) and Heather Stone (F 8:15 • Keynote: Jacqueline Corrigan -Curay (FDA) | 8:15-8:45 • **Cochairs: Jagdeep Podichetty (C-Path) & Matthew Robinson (JHU** • EHRs Data Extraction ○ Danielle Boyce (JHU) – Pulling structured data and the Edge too ○ Wes Anderson (C-Path) Unstructured data using AWS NLP | 9?0 ○ Ruth Kurtycz (CDC) – Propensity score modeling |9:15-9:30 ○ Kerry Howard (Clemson) – Lasso regression | 9:30-9:45 Break | 9:45-10:00 Moderators: Ewy Mathe (NCATS) & Raghav Tirupathi (C-Path) • Smitty Heavner (C-Path) – Analysis of initial COVID results | 10:00-10 • Roundtable: Discussion of results of Edge tool extraction and analysis | ○ Laura Evans (SCCM) ○ Nathalie Strub-Wourgaft (DNDi) ○ Matt Robinson (JHU) ○ Anup Challa (AstraZeneca) • Wrap up and next steps |11:45-12:00

April 19 PM	Lunch | 12:00-1:00
	
	Challenges and opportunities for confirming hypothesis generated by real-wo repurposed drugs through randomized clinical trials.
	
	<u>Afternoon: Pragmatic adaptive platform trials</u>
	
	• Welcome and Overview: Marco Schito (C-Path) and Heather Stone (FI
	• Keynote: David Fajgenbaum (Every Cure and CDRC AC Co-Chair) | 1
	• **Cochairs: Marco Schito (C-Path) and Leonard Sacks (FDA)**
	• Undiagnosed Diseases Network (UDN): Discovering Rare Disease The Through Team Science| 1:45-2:00
	
	Moderators: David Fajgenbaum (U Penn) and Heather Stone (FDA)
	
	• Critical considerations for clinical trials in DR | 2:00-2:15
	• Roundtable Discussions on decentralized trials and embedding trials in practice.
	  ○ Inpatient trials and innovations in embedding trials in practice | 2
	• Panelists:
	  ○ Trevan Locke (Duke Margolis)
	  ○ Jon Sevransky (Emory)
	  ○ Raghave Tirupathi (WellSpan Health)
	  ○ Stacey Coe (C-Path)
	  ○ Barbara Goodman (Cures within Reach)
	  ○ Cynthia Adinig (Patient)
	
	Break | 3:15-3:30
	
	• Outpatient/decentralized/patient-centric trials | 3:30—4:30
	  ○ Chris Lindsell (Duke)
	  ○ Nathalie Strub -Wourgraft (DNDi)
	  ○ Suanna Buinooge (ASCO)
	  ○ Oved Amitay (Solve CFS)
	  ○ Amy Morris (Emory)
	  ○ Vidula Sukhatme (GlobalCures)
	• Wrap up and next steps | 4:30-4:45
	
	Evening: Reception | 6:00-9:00
	
	• Poster Session
	• Keynote: Patient advocate
	• Hors d'oeuvres
	• Open bar
	• Taco stand
	• **Join Zoom Meeting: https://c-path-org.zoom.us/j/93756638801?pwd=ZXVhZmJwUkczWU1CaXRTO**
	  ○ **Meeting ID: 937 5663 8801**
	  ○ **Passcode: 225871**

April 20 AM	**<u>CDRC Annual Meeting Day 3: Thursday April 20</u>**
	
	• **Join via Zoom Meeting: https://c-path-org.zoom.us/j/93756638801?pwd=ZXVhZmJwUkczWU1CaXRTO**
	  ○ **Meeting ID: 937 5663 8801**
	  ○ **Passcode: 225871**
	
	Utility of generating real-world data for assessing repurposed drugs in rare c cancers.
	
	Morning: closed door meetings
	
	• CDRC Advisory Committee | 8:30-10:00 a.m.
	
	BREAK | 10:00-10:15 a.m.
	
	• Session with FDA and NIH | 10:15-11:45 a.m.
	
	LUNCH | 12:00-1:00

April 20 PM	**Afternoon: Rare Cancer (Sarcomas)**
	
	• Welcome Marco Schito (C-Path) (1:00-1:15)
	  ○ **Cochair**: Bill Tap (MSKCC)
	• CDRC plans for rare and ultrarare cancers | 1:15-1:45
	• Patient data: Denise Robinson (EHE Foundation | 1:45-2:00
	• RWD from EHRs: Mark Shapiro (xCures) | 2:00-2:15
	• Clinical trials: Clare Thibodeaux (Cures within Reach) | 2:15-2:30
	• Repurposed Drug Trials: Challenges and Opportunities: Vidula Sukhat (GlobalCures) | 2:30-2:45
	
	Break | 2:45-3:00
	
	Moderator: Marco Schito (C-Path)
	
	• Challenges and opportunities (Harnessing RWD to advance repurposed cancers) | 3:00-3:15
	• Panel Discussion | 3:15-3:45
	  ○ Brandi Felser (SFA)
	  ○ Christine Heske (NCI)
	  ○ Vidula Sukhatme (GlobalCures)
	  ○ Barbara Goodman (Cures within Reach)
	  ○ Andrea Gross (NCI)
	  ○ Suanna Bruinooge (ASCO)
	  ○ Lennie Woods (Clear Cell Sarcoma Foundation)
	• Next steps | 4:45-5:00
	
	Adjourn | 5:00