



An Introduction to FDA MyStudies: An Open-Source, Digital Platform to Gather Real World Data for Clinical Trials and Research Studies

May 9, 2019

AGENDA

Time	Topic	Presenter
10:00 a.m.	Welcome	CDER Small Business and Industry Assistance (SBIA)
10:05	Introduction to FDA MyStudies Mobile App System	David Martin, MD, MPH Associate Director for Real World Evidence Analytics Office of Medical Policy Center for Drug Evaluation and Research (CDER) FDA
10:15	A Demonstration of the FDA MyStudies Mobile App System: Patient and Researcher Experiences <ul style="list-style-type: none">• Mobile application• Web Configuration Portal (WCP)• Response and Registration Servers	Zachary Wyner, MPH <i>Senior Health Informatics Analyst</i> Department of Population Medicine Harvard Medical School & Harvard Pilgrim Health Care Institute
11:30	Break	
11:40	Questions and Answers	MyStudies Team
12:00 p.m.	Lunch Break	
12:30	Mobile Application and WCP: Usability and Technical Overview	Shyam Deval, MS, MBA <i>President & Chief Customer Officer</i> Boston Technology Corporation
		Ranjani Rao, MS <i>Chief Technology Officer</i> Boston Technology Corporation
1:10	Response Server Technical Overview	Adam Rauch <i>Vice President of Product Strategy</i> LabKey Software
1:30	Break	
1:45	Questions and Answers	MyStudies Team
2:10	Deploying the MyStudies System in a Compliant Manner	Stuart MacDonald <i>Director of Systems Engineering</i> LabKey Software
2:30	Questions and Answers	MyStudies Team
2:50	MyStudies Closing Remarks and Resources	MyStudies Team
2:55	Closing	CDER Small Business and Industry Assistance (SBIA)