Regulatory Science Symposium

Clinical Research Career Pathways

Friday, March 5, 2021 / 9am - 1pm PST

USC School of Pharmacy
International Center for Regulatory Science
SC CTSI

9:00 AM PST	**Introduction** *Eunjoo Pacifici, PharmD, PhD* USC, SC-CTSI, School of Pharmacy I Chair & Associate Professor, Dept. of Reg. & Quality Sciences l Associate Director, DK Kim lnternational Center for Regulatory Science
9:15 AM PST	**From Academics to Industry – A Physician Researcher Perspective** *Francine Kaufman, MD* Chief Medical Officer, Senseonics, Inc. I Distinguished Professor Emerita of Pediatrics at USC, The Center for Endocrinology, Diabetes & Metabolism, Children's Hospital Los Angeles
10:00 AM PST	**Clinical Supply Chain Management: Dude, Where's My Patient Benefit?** *Lequina Myles,DRSc, MS, MBA, RAC, PMP, PMI-ACP* Director, Quality Control at MARKEN
10:45 AM PST	**Break**
10:55 AM PST	**Understanding Clinical Research Management at Academic Institutions** *Zeno Ashai, MBBS, MPH* Associate Director, Clinical Investigations Support Office, University of Southern California
11:30 AM PST	**Roads to the Human Subjects Protection Program (OPRS and IRB)** *Julie Michele Slayton, JD, PhD* Director, Office for the Protection of Research Subjects (OPRS) I Clinical Professor, Rossier School of Education, University of Southern California
12:10 PM PST	**Knocking on HR's Door: Do you have what it takes to be a CRP?** *Elaine Fisher, PhD, RN, CNE* Director, Accreditation & Curriculum, Emory University, Nell Hodgson Woodruff School of Nursing *Rebecca Thomas, DNP, RN* Director of Clinical Research Nursing, Emory Healthcare
12:50 PM PST	**Wrap-Up** *Eunjoo Pacifici, PharmD, PhD* USC, SC-CTSI, School of Pharmacy I Chair & Associate Professor, Dept. of Reg. & Quality Sciences l Associate Director, DK Kim lnternational Center for Regulatory Science

Please complete the course evaluation survey at the end of the symposium to receive a certificate of completion. Hours may be eligible for SoCRA and/or ACRP credit.

Series sponsored by The Greater LA CTSA Consortium

UCLA CTSI Grant #UL1TR001881 | SC CTSI | UC•IRVINE ICTS from lab to life.

SC CTSI is part of the Clinical and Translational Science Awards (CTSA) , a national network funded through the National Center for Advancing Translational Sciences (NCATS) at the NIH (Grant Number UL1TR001855). Under the mandate of "Translating Science into Solutions for Better Health," SC CTSI provides a wide range of services, funding, and education for researchers and promotes online collaboration tools such as USC Health Sciences Profiles .

Regulatory Science Symposium:
Clinical Research Career Pathways
Speaker Bios

Eunjoo Pacifici (PharmD, PhD) is Chair and Associate Professor of Regulatory and Quality Sciences and Associate Director of the International Center for Regulatory Science. Dr. Pacifici received a BS in Biochemistry from the University of California Los Angeles and PharmD and PhD in Toxicology from the University of Southern California. She conducted her graduate research in the laboratory of Dr. Alex Sevanian in the Institute for Toxicology where she studied the mechanism of oxidative damage and repair in endothelial cell membrane. Before returning to USC as faculty, Dr. Pacifici worked at Amgen and conducted clinical research with a special focus on Asia Pacific and Latin America. She initially worked in the clinical development group managing U.S. investigational sites and central laboratories, then in the Asia Pacific / Latin America group interfacing with local clinical and regulatory staff in Japan, the People's Republic of China, Taiwan, and Mexico. She represented regional clinical and regulatory views on therapeutic product development teams and led satellite task forces to align local efforts with U.S. activities. Her professional experience includes community pharmacy practice in various settings and clinical pharmacy practice at the Hospital of the Good Samaritan in Los Angeles. Her current focus is on developing the next generation of regulatory scientists and pharmacy professionals with the knowledge, tools, and skills to expedite the development of innovative, safe, and effective biomedical products. epacific@usc.edu

Francine R. Kaufman (MD) is Chief Medical Officer of Senseonics, Inc. where she concentrates on global clinical strategy for the Eversense Continuous Glucose Monitoring System, the first long-term implanted glucose sensor. From 2009-2019, she was Chief Medical Officer and Vice President of Global Regulatory, Clinical and Medical Affairs at Medtronic Diabetes where she was responsible for clinical and regulatory strategy for the MiniMed 670G hybrid closed loop system, the first automated insulin device. Under her leadership, the 670G device gained FDA approval in 2017. She is a Distinguished Professor Emerita of Pediatrics and Communications at the USC Keck School of Medicine and the Annenberg School of Communications. She is an attending physician at Children's Hospital of Los Angeles, where she served as Director of the Comprehensive Childhood Diabetes Center and head of the Center for Endocrinology, Diabetes and Metabolism. Dr. Kaufman was national president of the American Diabetes Association from 2002-2003 and elected membership in the National Association of Medicine of the National Academies of Science. She was appointed by Congress as a Local Legend with the American Woman's Medical Association. In 2009, she received a Telly and CINE for starring in and co-authoring the Discovery Health Documentary, *Diabetes: The Global Epidemic*. fkaufman@chla.usc.edu

Lequina Myles (DRSc, MS, MBA, RAC, PMP, PMI-ACP) is Director of Quality Control at MARKEN providing quality oversight for international and domestic life science, medical product, and clinical trial supply chain management and distribution. Her career started in the Quality Control Biochemistry Laboratories managing and supporting global projects, which increased organizational efficiency, productivity while improving client retention and strategic partnerships. Lequina holds a B.S. in Biochemistry from the University of California, Los Angeles, a Master of Business Administration (MBA) with an emphasis in Project Management from Mount Saint Mary's University, a Masters in Regulatory Science and Doctor of Regulatory Science (DRSc) at the University of Southern California. She is a certified Project Management Professional and holds a Regulatory Affairs Certification (RAC) in both drugs and devices. In addition to industry experience, Lequina is an Adjunct Faculty in the MBA Program at Mount Saint Mary's University and serves as a guest lecturer at the School of Pharmacy, USC. lmyles@usc.edu

Zeno Ashai (MBBS, MPH) is the Associate Director of the Clinical Investigations Support Office (CISO) at the USC Norris Comprehensive Cancer Center (NCCC). Mrs. Ashai dedicated over 15 years in oncology clinical research, 13 years of which have been in complex, multi-layered academic environment of the NCI-designated cancer center. Mrs. Ashai has worked in the pharmaceutical industry as Director of Clinical Operations with special focus in oncology in US, India and Latin America, successfully advancing two oncology compounds through Phase I and II clinical trials. As part of her role, Mrs. Ashai was managing U.S. investigational sites and central laboratories as well as Global CROs, interfacing with FDA, local regulatory and clinical entities to ensure compliant and timely conduct of clinical trials. In 2010 Mrs. Ashai joined the USC NCCC CISO leadership team as Assistant Director for Regulatory working within a multidisciplinary team to further expand the regulatory and PRMS programs. In 2019 Mrs. Ashai was promoted to Associate Director of CISO where she now leads CISO Clinical Research, Regulatory, Business Administration and QA teams ensuring safe and compliant implementation of Phase I, II and III oncology clinical trials conducted at USC. Her areas of expertise include management and implementation of clinical trial operations, quality assurance, FDA regulations, regulatory compliance, and development and implementation of operating policies & procedures for conducting clinical trials in academic setting. Mrs. Ashai completed medical school at Fatima Jinnah Medical College in Pakistan followed by residency training. She holds a Master's degree in Public Health Administration and Policy from the University of Minnesota. zeno.ashai@med.usc.edu

Julie Slayton (JD, PhD) is Director of the Office for the Protection of Research Subjects. She is responsible for AAHRPP re-accreditation, reviewing and developing policies, identifying and implementing best practices, and fostering research ethics education for USC. Dr. Slayton previously served as the Chair of the University Park Campus Institutional Review Board and currently serves as a member of the faculty and planning committee faculty for the Public Responsibility in Medicine and Research (PRIM&R) Conference. Dr. Slayton is Professor of Clinical Education at USC Rossier, where she teaches in the Leadership EdD program. She is a qualitative researcher, focusing on the quality of instruction provided to children in elementary school classrooms and adults in professional development settings. Prior to her tenure at USC, Dr. Slayton worked for the Los Angeles Unified School District as the Director for Research and Planning and the Executive Director for the Office of Strategic Planning and Accountability, where she directed research and policy analysis related to the implementation of instructional policies and programs in the District. In addition, Dr. Slayton practiced law and was a consultant for the U.S. Department of Justice, Office of Juvenile Justice and Delinquency Prevention on Federal and State laws pertaining to students' constitutional rights on campus and inter-agency information sharing regarding juveniles who are at risk of or already engaged in delinquent behavior. She holds a BA from the University of California, San Diego, a J.D. from Pepperdine University School of Law, and a Ph.D. from the U.C.L.A. Graduate School of Education and Information Studies. jslayton@usc.edu

Elaine Fisher (PhD, RN, CNE) is Director of Accreditation, Curriculum and Registration and Clinical Professor of Nursing at the Emory University Nell Hodgson Woodruff School of Nursing. Before joining Emory University, she received several grants for her bench research on detecting and monitoring changes in gut oxygenation under hypoxic and anoxic conditions with a focus on translation to the clinical setting. Dr. Fisher is the Education Coordinator for the Georgia Clinical and Translational Science Alliance (Georgia CTSA), Translational Workforce Development (TWD) grant. Her work on this grant focuses on the development of a career navigation system for clinical research professionals (STELLAR); and in conjunction with USC – CTSI, the development of a free TWD Course Catalog with high quality programs and courses offering certificates and badges to advance training of clinical research professionals. Her current focus is on creating artificial intelligence and machine learning solutions for better matching of CRC candidates to PI and research project needs. elaine.fisher@emory.edu

Rebecca Thomas (DNP, RN) is Director of Clinical Research Nursing at Emory Healthcare and serves as the Nursing Director for the outpatient research units for the Georgia Clinical and Translational Science Alliance (Georgia CTSA). She has worked across multiple disease sites, both clinically and in research. Her expertise in clinical research spans over 16 years and has over 15 years of experience in critical care nursing. Dr. Thomas is the Trainer for Georgia CTSA Translational Workforce Development Project (TWD) grant. Her work on this grant focuses on the development of a career navigation system for clinical research professionals
(STELLAR). rebecca.thomas@emoryhealthcare.org

Regulatory Science Virtual Symposium

Clinical Research Career Pathway

Introduction

Eunjoo Pacifici, PharmD, PhD
Chair and Associate Professor, Regulatory and Quality Sciences
Associate Director, DK Kim International Center for Regulatory Science

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SC CTSI Clinical Research Support (CRS)

A single stop for accessing all services an Investigator and research team needs to develop, activate, conduct, and report results for human subject research studies

Initial focus on investigator-initiated trials (non-cancer)

- **Services:**
  - Clinical research coordinators for hire
  - Research navigation
  - Recruitment support
  - Budget preparation support
- **Clinical Trials Unit (CTU)**:
  - Skilled research and nursing staff
  - Services to support highly-complexed human subjects research studies
  - Specimen processing lab
- **Voucher program:**
  - Awards up to $3,000 to generate new data for development of clinical and/or community research projects

https://sc-ctsi.org/about/groups/clinical-research-support

Nicki Karimipour, PhD
Program Manager
CRS

Lily Jara, BS
Clinical Research Supervisor
CRS

Contact Information:
crs@sc-ctsi.org

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Monitoring Module

1. Go to: https://uscregsci.remote-learner.net
2. Click ***create new account*** (right-hand side)
3. Type in your information and click ***Create my new account*** (bottom of page)
4. Open your email and click the link to confirm your account
5. Click ***courses*** (middle of page)
6. Scroll down and click ***Module 1 – Clinical Trial Monitoring***
7. Click ***Enroll me*** (middle of page)

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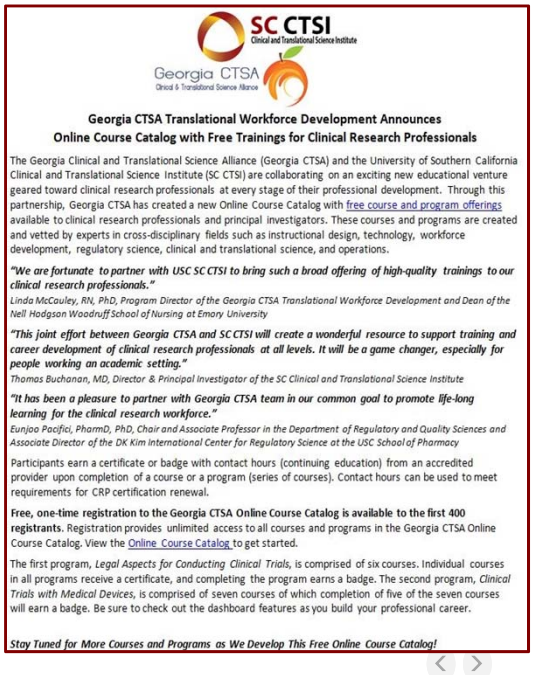
Georgia CTSA and SC CTSI: Online Course Catalog

- Free trainings for clinical research workforce
- Free, one-time registration to the first 400 registrants
- Registration provides unlimited access to all courses and programs in the Online Course Catalog
- Participants earn a certificate or badge with contact hours upon completion of a course or program
- Contact hours can be used for CRP certification renewal
- To get started:

https://twd.ce.emorynursingexperience.com/



SC CTSI Clinical and Translational Science Institute
Georgia CTSA Clinical & Translational Science Alliance

Georgia CTSA Translational Workforce Development Announces Online Course Catalog with Free Trainings for Clinical Research Professionals

The Georgia Clinical and Translational Science Alliance (Georgia CTSA) and the University of Southern California Clinical and Translational Science Institute (SC CTSI) are collaborating on an exciting new educational venture geared toward clinical research professionals at every stage of their professional development. Through this partnership, Georgia CTSA has created a new Online Course Catalog with free course and program offerings available to clinical research professionals and principal investigators. These courses and programs are created and vetted by experts in cross-disciplinary fields such as instructional design, technology, workforce development, regulatory science, clinical and translational science, and operations.

"We are fortunate to partner with USC SC CTSI to bring such a broad offering of high-quality trainings to our clinical research professionals."
Linda McCauley, RN, PhD, Program Director of the Georgia CTSA Translational Workforce Development and Dean of the Nell Hodgson Woodruff School of Nursing at Emory University

"This joint effort between Georgia CTSA and SC CTSI will create a wonderful resource to support training and career development of clinical research professionals at all levels. It will be a game changer, especially for people working an academic setting."
Thomas Buchanan, MD, Director & Principal Investigator of the SC Clinical and Translational Science Institute

"It has been a pleasure to partner with Georgia CTSA team in our common goal to promote life-long learning for the clinical research workforce."
Eunjoo Pacifici, PharmD, PhD, Chair and Associate Professor in the Department of Regulatory and Quality Sciences and Associate Director of the DK Kim International Center for Regulatory Science at the USC School of Pharmacy

Participants earn a certificate or badge with contact hours (continuing education) from an accredited provider upon completion of a course or a program (series of courses). Contact hours can be used to meet requirements for CRP certification renewal.

Free, one-time registration to the Georgia CTSA Online Course Catalog is available to the first 400 registrants. Registration provides unlimited access to all courses and programs in the Georgia CTSA Online Course Catalog. View the Online Course Catalog to get started.

The first program, *Legal Aspects for Conducting Clinical Trials*, is comprised of six courses. Individual courses in all programs receive a certificate, and completing the program earns a badge. The second program, *Clinical Trials with Medical Devices*, is comprised of seven courses of which completion of five of the seven courses will earn a badge. Be sure to check out the dashboard features as you build your professional career.

Stay Tuned for More Courses and Programs as We Develop This Free Online Course Catalog!

Webpage: http://regulatory.usc.edu

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Degree Programs

Five Graduate Streams

- DRSC
- **MS Regulatory Science**
- MS Regulatory Management
- MS Management of Drug Development
- MS Medical Product Quality

Certificates

- Food safety
- Regulatory Science
- Early Drug Development
- **Clinical Design and Management**
- Patient and Product Safety

Nancy Smerkanich
DRSc, MS

Assistant Professor
Department of Regulatory and Quality Sciences

piresmer@usc.edu

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Symposiums

- **2015 -** Clinical Trial Hurdles
- **2016 Spring** - Clinical Trial Startup
- **2016 Fall** - Monitoring and Auditing
- **2017 Spring** - Clinical Trials in Special Populations
- **2017 Fall** - Clinical Trials in Era of Emerging Technologies and Treatments
- **2018 Spring** - Regulatory Aspects of Clinical Trial Design
- **2018 Fall** - Pharmacovigilance and Safety Reporting
- **2019 Spring** - Patient-Centered Drug Development and Real World Evidence/Data
- **2019 Summer** - Clinical Trials with Medical Devices
- **2019 Fall** - Legal Aspects of Conducting Clinical Trials
- **2020 Spring** - Quality by Design in Clinical Trials
- **2020 Fall –** Diversity in Clinical Trials in the Time of COVID-19
- **2021 Spring** – Clinical Research Career Pathways
- **2021 Summer** – Principles of Global Clinical Research for Medical Devices

Symposium recordings are easily accessible for viewing on the SC CTSI's online educational library
https://sc-ctsi.org/training-education/courses?audience=researchProfessionals

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Clinical Research Career Pathways

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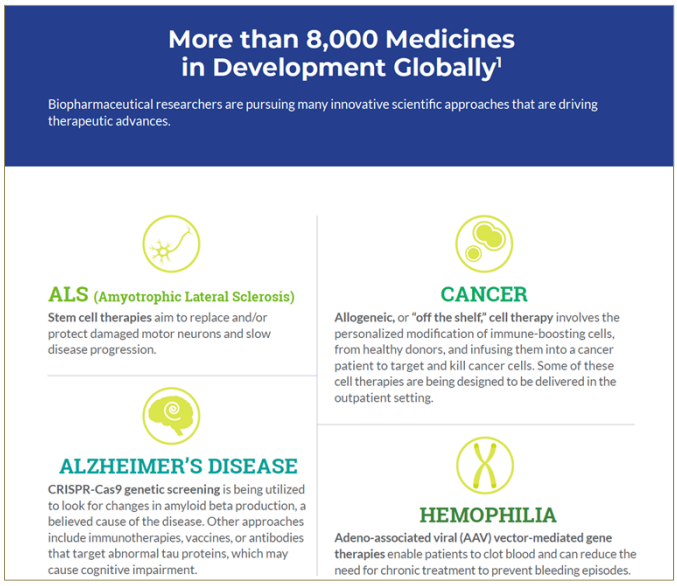
Need for Skilled Workforce

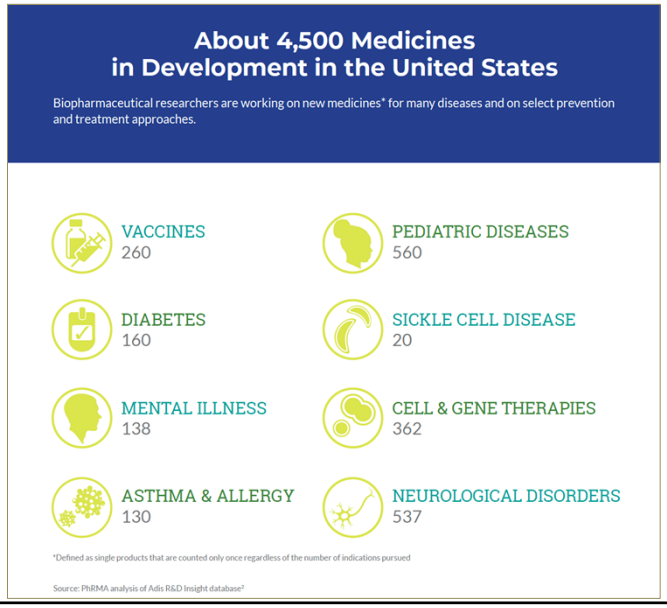


Number of Current Active Clinical Trials in U.S.*

Condition or Disease	Active not yet Recruiting	Recruiting/Enrolling	Total
Cancer (all types)	6,501	16,717	23,218
Psychiatric Disorders	1,114	4,838	5,952
COVID-19	412	2,593	3,005
Diabetes (all types)	599	1,924	2,523
Cerebrovascular Disease	245	1,329	1,574
Hypertension (all types)	260	1,119	1,379
Vaccines	452	758	1,210
Alzheimer's Disease (all stages)	127	498	625

*Data from Clinicaltrials.gov, current as of 3 March 2021

Across all Therapeutic Areas



Agenda

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12:50 PM PST	**Wrap-Up** *Eunjoo Pacifici, PharmD, PhD* USC, SC-CTSI, School of Pharmacy I Chair & Associate Professor, Dept. of Reg. & Quality Sciences I Associate Director, DK Kim International Center for Regulatory Science

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Presented by the USC School of Pharmacy International Center for Regulatory Science and the Southern California Clinical and Translational Science Institute

This certifies that

Before the end of todays Symposium you will receive a link to take the program evaluation.

Follow this link to the Survey:
Take the Survey

Please complete the program evaluation to receive a certificate of completion by Friday, March 19, 2021.

Eunjoo Pacifici, PharmD, PhD
Director
International Center for Regulatory Science

Thomas A. Buchanan, MD
Director
Southern California Clinical and Translational Science Institute

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Facebook: @RegSci

From Academics to Industry – A Physician Researcher Perspective

Francine R. Kaufman, MD

Chief Medical Officer, Medtronic Diabetes
VP Global Medical, Clinical and Regulatory Affairs
Distinguished Professor Emerita, The Keck School of Medicine of the University of Southern California and Children's Hospital Los Angeles

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I have Been Around for a Long Time – in Diabetes Research and Care

My Career: From Clinical, to Basic, to Clinical, to Diabetes Camp, to Public Health Research, at Children's Hospital LA and then to Industry – Medtronic, Senseonics

ADA President 2003

I Helped Ban Soda in LA Unified School District

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The Team who Brought Forth the Closed Loop

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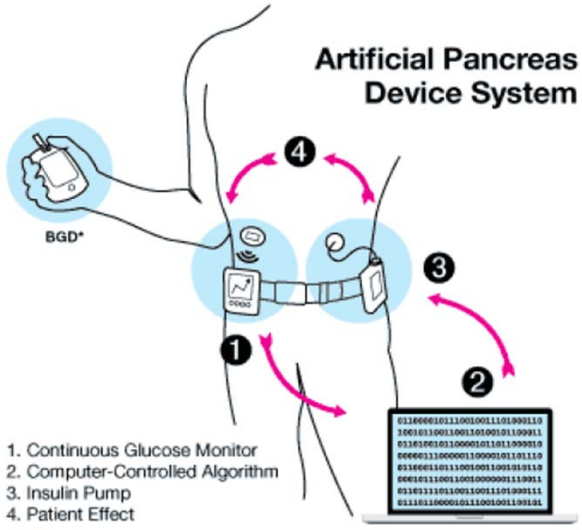

My career path brought me to the journey of developing the artificial pancreas

The question to be answered: Can connected devices and an algorithm better regulate insulin delivery matched to glucose levels than patients/clinicians?

What would need to be done for patient/clinician acceptance?

What would be the regulatory pathway to a commercial device?

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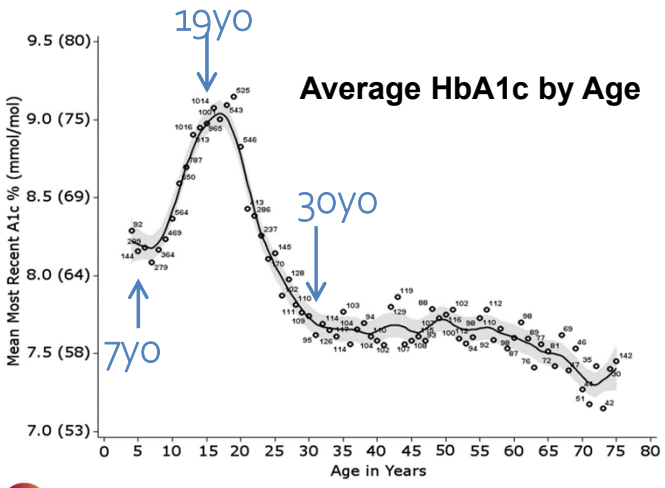
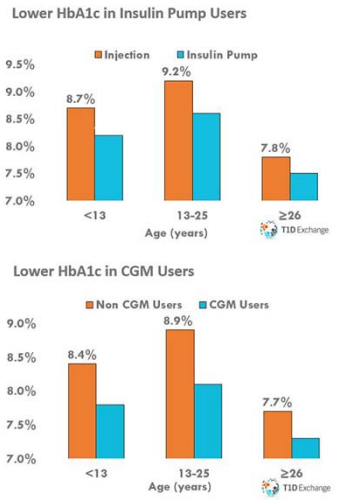
The need for the artificial pancreas

NOT AT GOAL, TECHNOLOGY HELPS



Technology Helps



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Miller, et al. Diab Care Jun 2015. 38(6): 971-978.
T1D Exchange Clinic Registry

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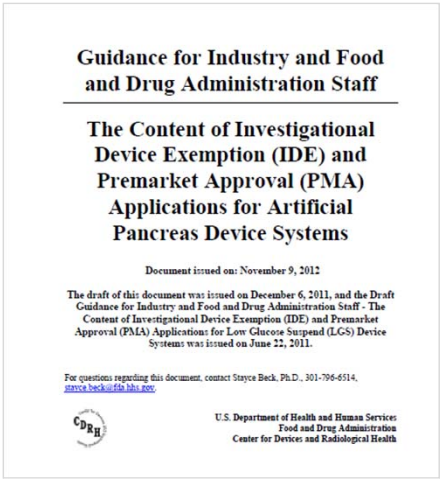
Pathway forward



Guidance for Industry and Food and Drug Administration Staff

The Content of Investigational Device Exemption (IDE) and Premarket Approval (PMA) Applications for Artificial Pancreas Device Systems

Document issued on: November 9, 2012

The draft of this document was issued on December 6, 2011, and the Draft Guidance for Industry and Food and Drug Administration Staff - The Content of Investigational Device Exemption (IDE) and Premarket Approval (PMA) Applications for Low Glucose Suspend (LGS) Device Systems was issued on June 22, 2011.

For questions regarding this document, contact Stayce Beck, Ph.D., 301-796-6514, stayce.beck@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Components of exploration, verification, validation

- Laboratory study
- Preclinical study
- In-silico study
- Early feasibility clinical study
- Late feasibility clinical study
- Pivotal clinical study
- Post-approval study

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Automated Suspend

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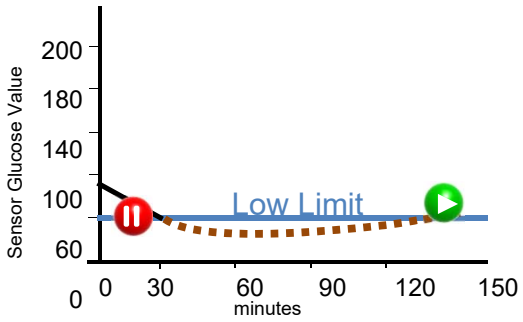
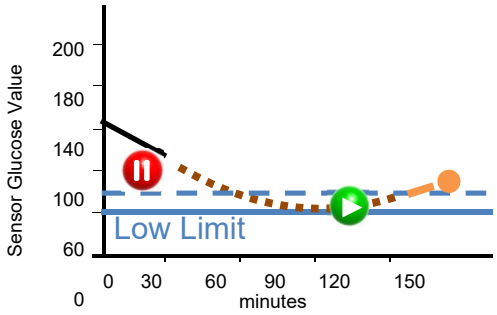
Evidence building

SUSPEND THRESHOLD AND PREDICTED SUSPEND -

Who was involved, engineers, regulatory, quality, manufacturing, marketing, clinical trial leaders and staff, statisticians, project managers, physician researchers, clinical trial sites – staff in a number of sites able to induce hypoglycemia and allow for safety





64% OF ALL THRESHOLD SUSPEND EVENTS ARE <30 MIN

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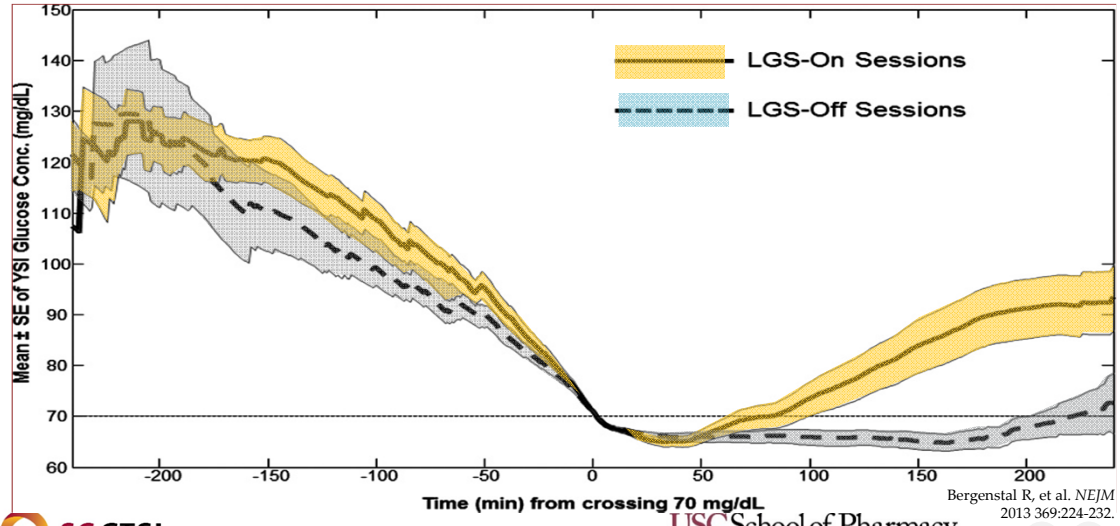
Aspire trial results

IN CLINIC RESULTS

CLINICAL EVIDENCE FOR LOW SUSPEND FEATURE

Garg S, et al. *Diabetes Technol Ther.* 2012;14:205-209



Bergenstal R, et al. *NEJM* 2013 369:224-232.

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HYBRID CLOSED LOOP

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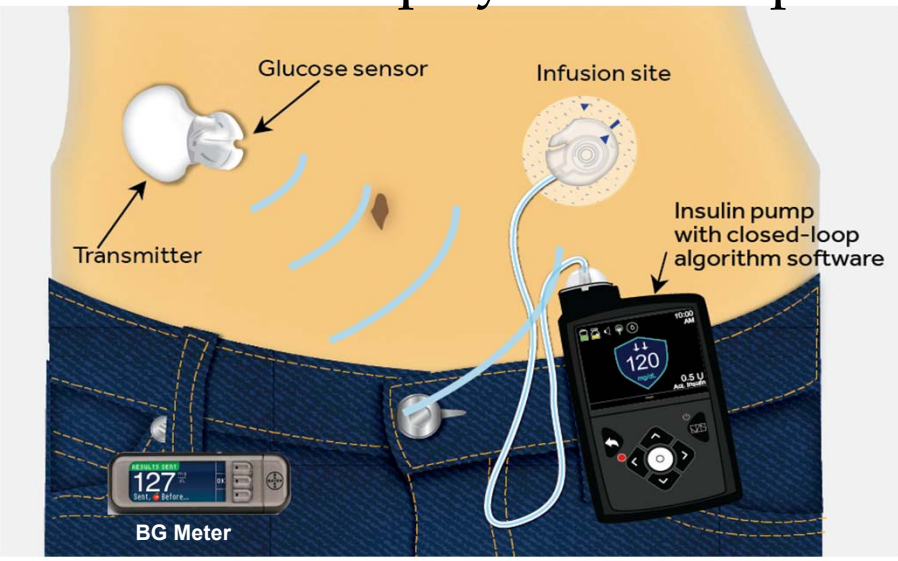
Hybrid closed loop system components



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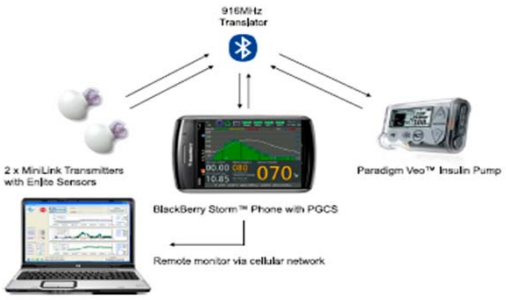
Closed loop early studies

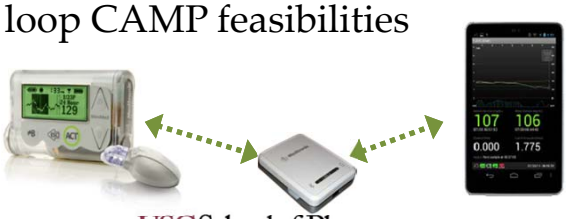
EARLY INVESTIGATION

Overnight closed loop in Clinic

- A number of early prototypes
- A number of early studies
- Approved by FDA for feasibility



Day and Night closed loop CAMP feasibilities



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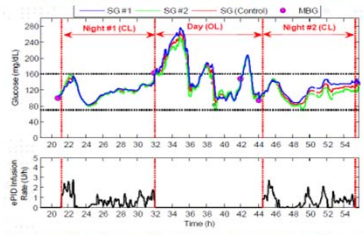
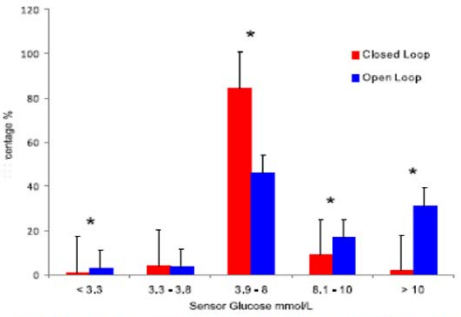
Closed loop at night

Overnight Closed-Loop In-Clinic, In-Home, In-Clinic

The Overnight Period is without disturbances of Food and Activity with

OVER 80% OF TIME IN TARGET 70-180 MG/DL (3.9-10.0 MMOL/L)





ure 3—*Comparison of overnight closed-loop (red) with prestudy open-loop (blue) control.*
< 0.0001.

D'Grady, et al, Perth, Australia Diabetes Care, DOI:10.2337/dc12-0761 2012

Not approved in US.

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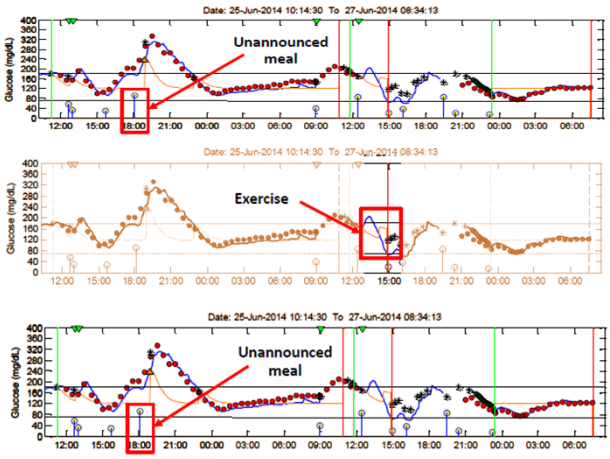
Following FDA guidelines

Treat to Target: 120 mg/dL

CHALLENGE TESTING - FEASIBILITY STUDIES:

- Exercise
- Unannounced meals
- Sensor false calibration
- Lost transmission
- Maximal insulin delivery

- Intense studies done in clinics with able staff for safety and data collection – critical to success
- Our team employed, along with the teams at the clinical sites



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In-Camp Studies – Dr. Buckingham and Dr. Ly

Buckingham Camp Study, 2013 Used by Permission

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THE PIVOTAL HYBRID CLOSED LOOP TRIAL

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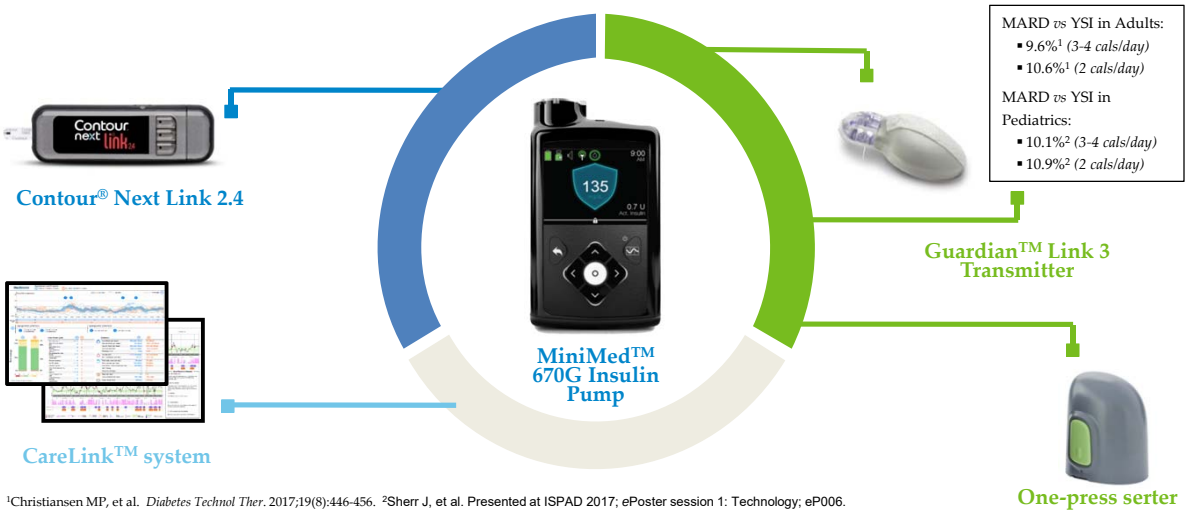
MINIMED™ 670G SYSTEM WITH SMARTGUARD™ TECHNOLOGY
HYBRID CLOSED LOOP



[1]Christiansen MP, et al. *Diabetes Technol Ther*. 2017;19(8):446-456. [2]Sherr J, et al. Presented at ISPAD 2017; ePoster session 1: Technology; eP006.

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HYBRID CLOSED LOOP PIVOTAL TRIALS
SINGLE-ARM, NON-RANDOMIZED STUDIES- (2016)14-75 YRS; (2017) 7-13 YRS; ONGOING

Inclusion criteria 14 – 75 years[1,2]	Inclusion criteria 7 – 13 years*	Inclusion criteria 2 – 6 years*
▪ 10 sites (9 US, 1 Israel) -124 subjects ▪ Type 1 diabetes > 2 years ▪ HbA1C <10% - mean HbA1C 7.4% ▪ Adolescents 14-17 Years (n=20) ▪ Young adults 18-21 Years (n=10)	▪ 9 sites (8 US, 1 Israel) -105 subjects ▪ Type 1 diabetes > 1 year ▪ HbA1C <10% - mean HbA1C 7.9% ▪ Pump ≥6 months, +/-CGM – 66% + CGM	▪ ~7 sites - 50 subjects ▪ Type 1 diabetes > 3 months ▪ HbA1C <10% ▪ Pump ≥3 months, +/-CGM

Study Patient Flow

Baseline Enrollment → Run-in Phase (2 weeks) (SAP Only) → Hotel Study (1 week) Each site, 1/3 of patients → In – Home (3 months) → HbA1C and Hypoglycaemia rates, AUC

Hotel in month 2 and 3 for remaining 2/3 of patients

Hypoglycemia Induction for Suspend before low Feature

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*Investigational use only. Approved for use in people with type 1 diabetes aged 14 and older.

[1]Bergenstal RM, et al. *JAMA*. 2016;316(13):1407-1408. [2]Garg SK, et al. *Diabetes Technol Ther*. 2017;19(3):155-163.

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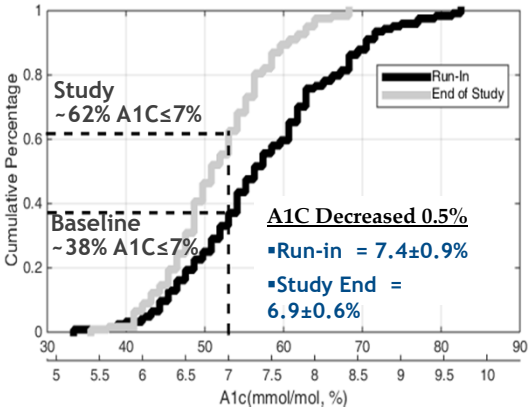
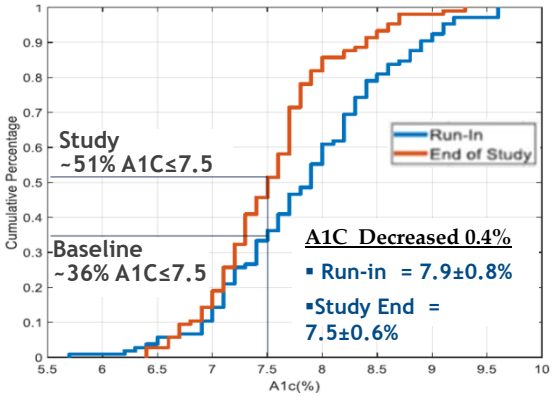
CHANGE IN A1C DISTRIBUTION FROM RUN-IN TO STUDY END

Adults and Adolescents (14-75 yrs) [1,2]
N= 124



87.2% Auto Mode Use

Children (7-13 yrs)*
N= 105



79.4% Auto Mode Use

1. Bergenstal RM, et al. *JAMA*. 2016;316(13):1407-1408.
2. Garg SK, et al. *Diabetes Technol Ther*. 2017;19(3):155-163.
* Data on file with Medtronic, presented at ADA, EASD, ISPAD, 2018

Forlenza G, et al, DIABETES TECHNOLOGY & THERAPEUTICS
Volume 21, Number 1, 2019 DOI: 10.1089/dia.2018.0264

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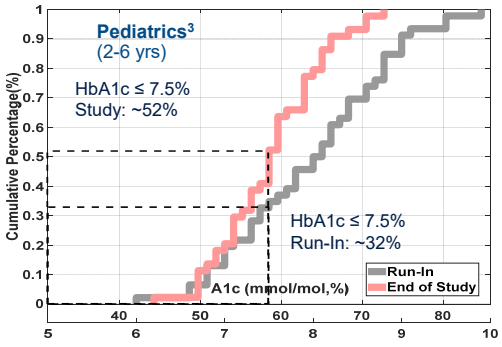
MINIMED™ 670G system pivotal STUDIES

HBA1C DISTRIBUTION



PIVOTAL STUDY
2-6 year old subjects
6,697 patient days

Starting HbA1c – 8.0%
Study End HbA1c – 7.5%

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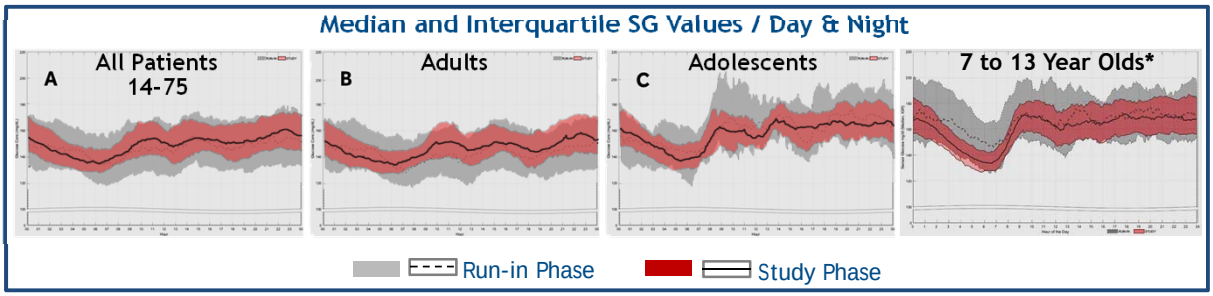
MOVING BEYOND A1C: REDUCED GLYCEMIC VARIABILITY

PIVOTAL HCL TRIAL

HCL Utilization (% of time)

Adults = 88.0% **Adolescents = 75.8%** **Children = 79.4%**



Due to inherent study limitations, caution is advised when attempting to extrapolate these results to new patients. There could be significant differences.

[1]Bergenstal RM, et al. *JAMA*. 2016;316(13):1407-1408. [2]Garg SK, et al. *Diabetes Technol Ther*. 2017;19(3):155-163.

Forlenza G, et al, DIABETES TECHNOLOGY & THERAPEUTICS
Volume 21, Number 1, 2019 DOI: 10.1089/dia.2018.0264

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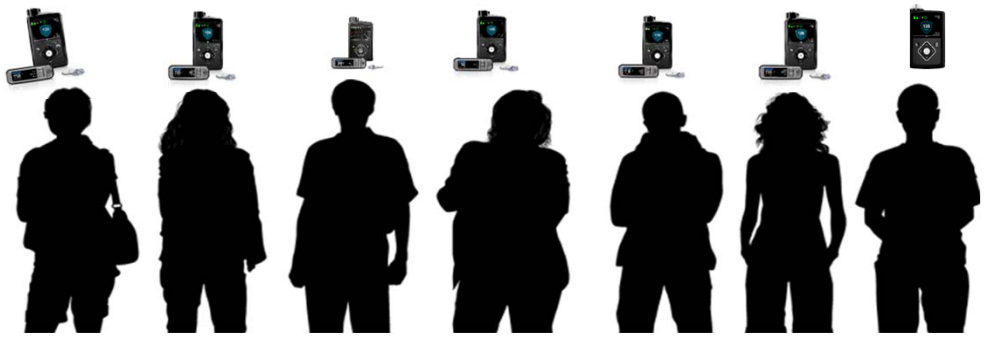
~14,350 PATIENTS ON MINIMED™ 670G SYSTEM



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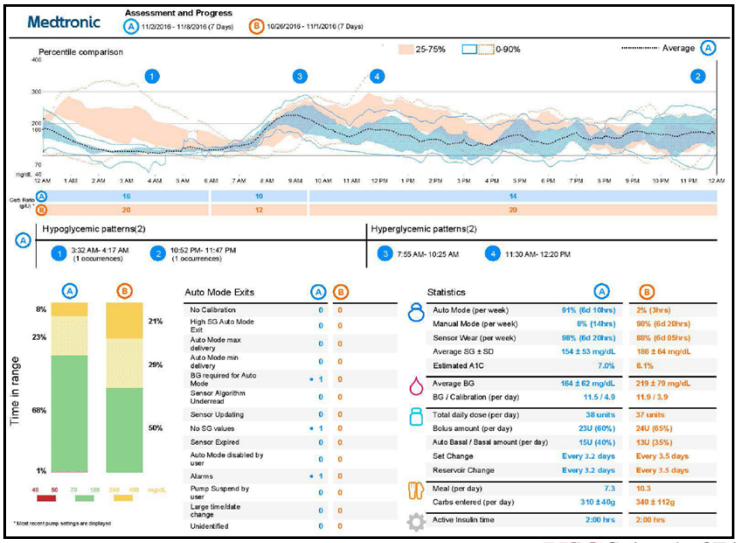
Putting it all together – 14-year old boy
IMPROVEMENT IN GLYCEMIA



- In Auto Mode >80%
- Lows <3% (<70 mg/dL)
- More Bolus than Basal

- Stronger Carb Ratio
- Still Post Meal Elevation, Patients Need to Expect This
- Responds Quickly to Exits

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COMMERCIAL LAUNCH COMPARED TO PIVOTAL TRIAL
FIRST ~1,000 PATIENTS

	Pivotal Trial[1,2]		Commercial Launch*			
	Manual Mode	Auto Mode	Manual Mode	Auto Mode Month 1	Auto Mode Month 2	Auto Mode Month 3
Patients, N	124	124	1052	1052	1052	1052
Auto Mode Use, %	-	87.20	-	88.60	86.78	85.96
Mean SG, mg/dL	150.2	150.78	157.02	149.84	150.30	150.75
Percentage of time in SG range, mg/dL						
<50	0.85	0.54	0.38	0.30	0.32	0.33
<54	1.33	0.81	0.60	0.46	0.50	0.52
<70	5.47	3.04	2.65	2.07	2.21	2.23
70-180	66.74	72.4	67.39	75.00	74.36	74.07
>180	27.4	24.45	29.96	22.93	23.43	23.70
>250	6.94	5.58	7.49	4.50	4.86	5.14

*Data on file
[1]Bergenstal RM, et al. *JAMA*. 2016;316(13):1407-1408. [2]Garg SK, et al. *Diabetes Technol Ther*. 2017;19(3):155-163.

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NEXT STEP IN HYBRID CLOSED LOOP

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The future of diabetes management:

Automated therapy

FOR OPTIMIZED GLYCEMIC CONTROL

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dreamed DIABETES

Future Issues with Closed Loop

Still requires a group effort

Big data people
Researchers inside industry and at clinical research sites in academic centers
Regulatory/Quality
Engineers for further produce development
Software/hardware
Materials experts
Cloud computing
Marketing
Sales

The Eco-System of Closed Loop

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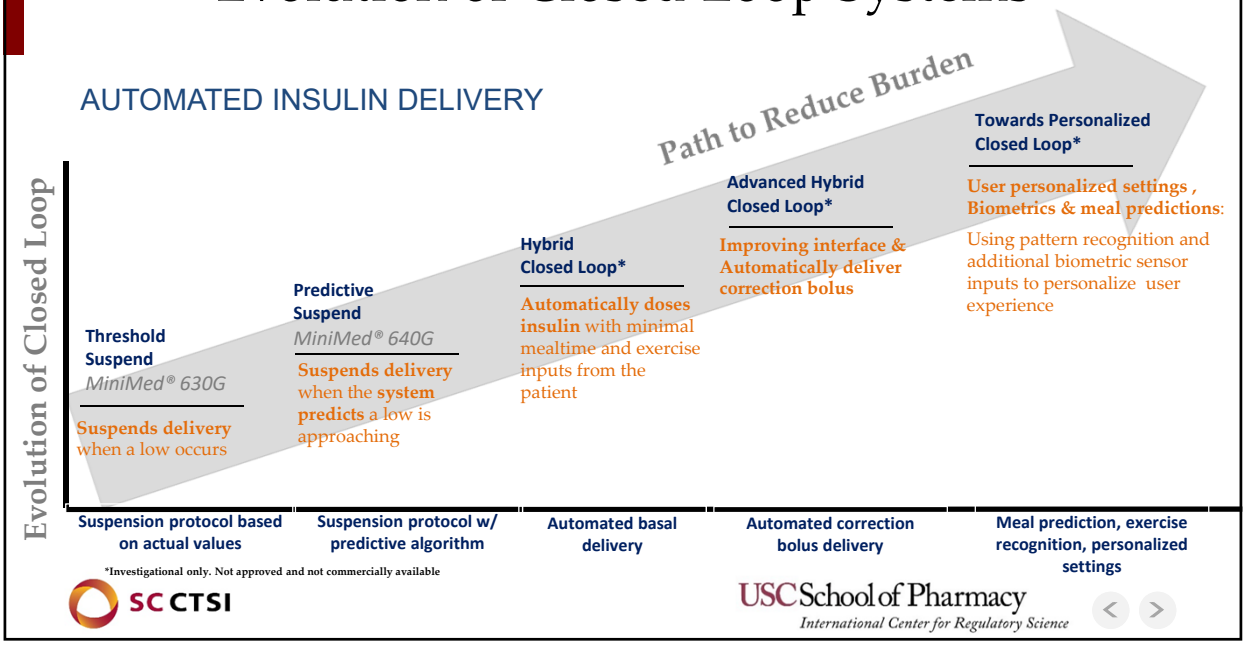
Evolution of Closed Loop Systems



*Investigational only. Not approved and not commercially available

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And Around the World – Kazakhstan

Insulin for Life – Brings supplies to children and during disasters

Life for a Child – the international program for children

Sponsorship Across the Globe
The IDF Life for a Child Program is currently helping over 12,000 CHILDREN AND YOUTH WITH DIABETES IN 43 COUNTRIES.

Life for a Child Program in Ethiopia – Teaching Standards of Care

Bangladesh – Stigma Against those with Diabetes

Diabetes in Children in Haiti

First Camp, 2011

Camps, 2012-14

Camps, 2015-17

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Clinical Supply Chain Management

Dude, Where's My Patient Benefit ?

Lequina Myles DRSc, MS, MBA, RAC, PMP, PMI-ACP
Director of Quality and Compliance, Americas

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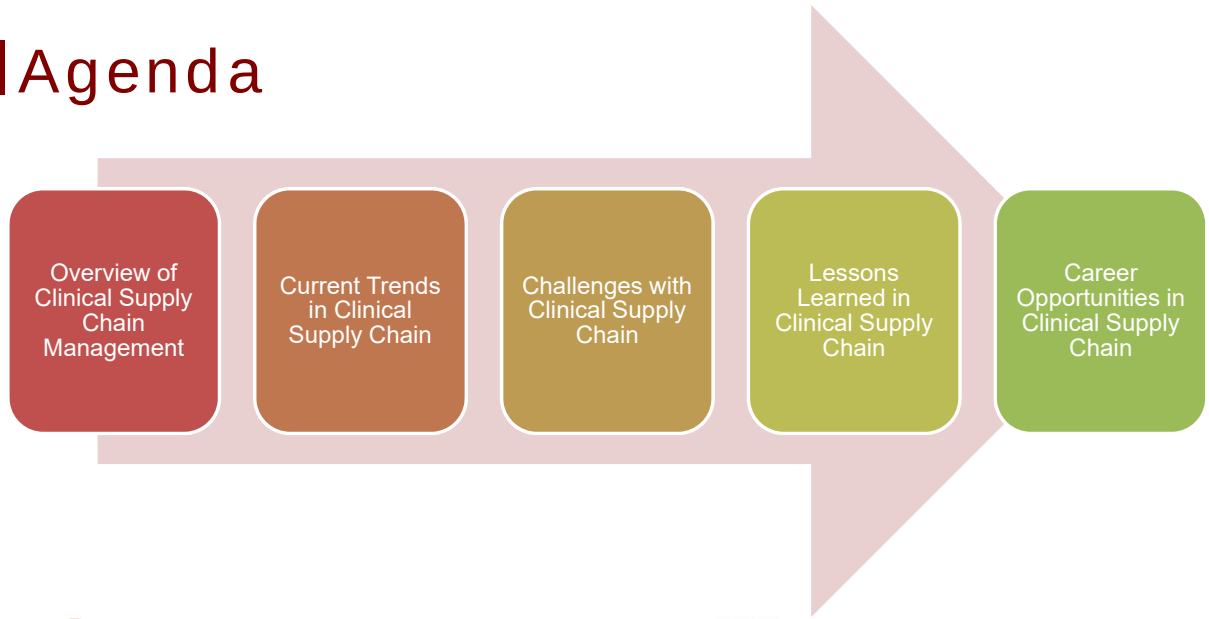
Agenda



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Objectives of Discussion

- General Overview of Clinical Supply Chain Management and how it fits into the Drug Development Cycle
- Understand Operational and Regulatory Landscape of Clinical Supply Chain
- Challenges and Opportunities for Clinical Supply Chain
- Clinical Supply Chain for Precision Therapies
- Supply Chain Management during COVID-19
- Career Outlooks in Clinical Supply Chain Supply Chain

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What is Supply Chain Management ?

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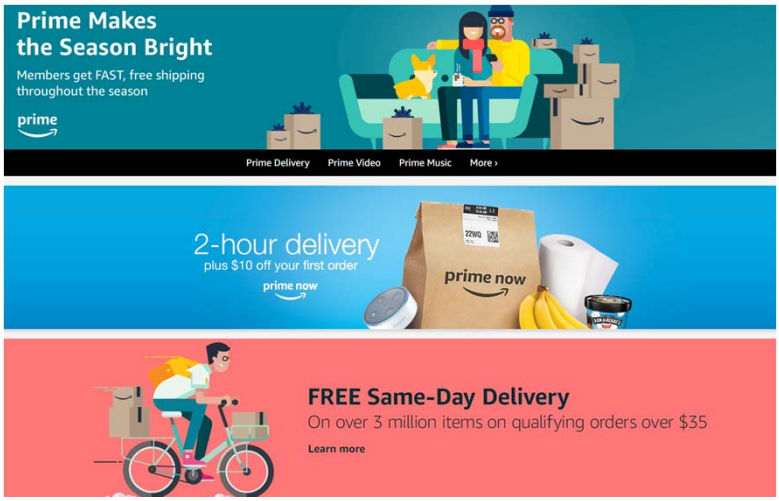
"Amazon" Effect



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Supply Chain Management

Supply chain management (SCM) is active management of supply chain activities required to plan, control and execute a product's flow, from acquiring raw materials and production through distribution to the final customer

- Physical Material Flow
- Flow of Information
- Financial Transactions

https://scm.ncsu.edu/scm-articles/article/what-is-supply-chain-management-scm

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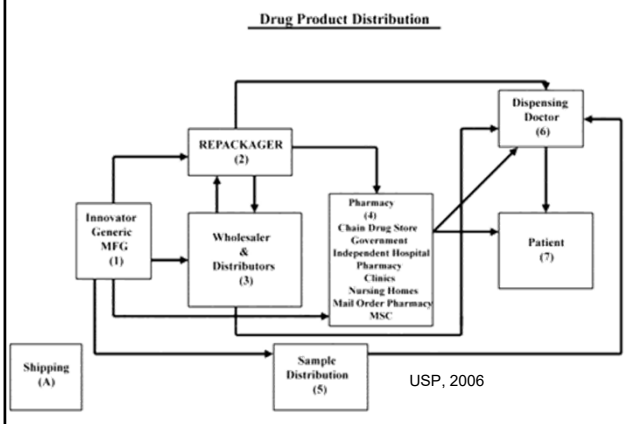
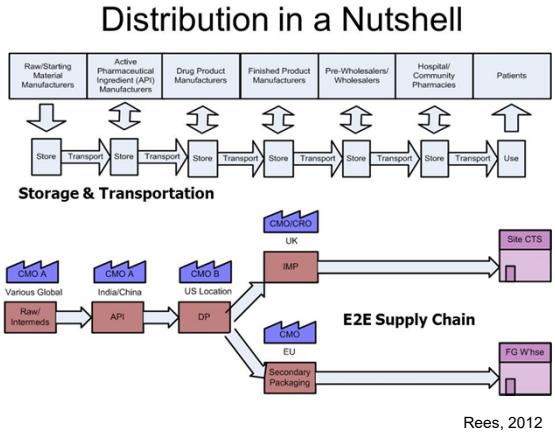
Pharmaceutical Supply Chain



USP, 2006



Rees, 2012

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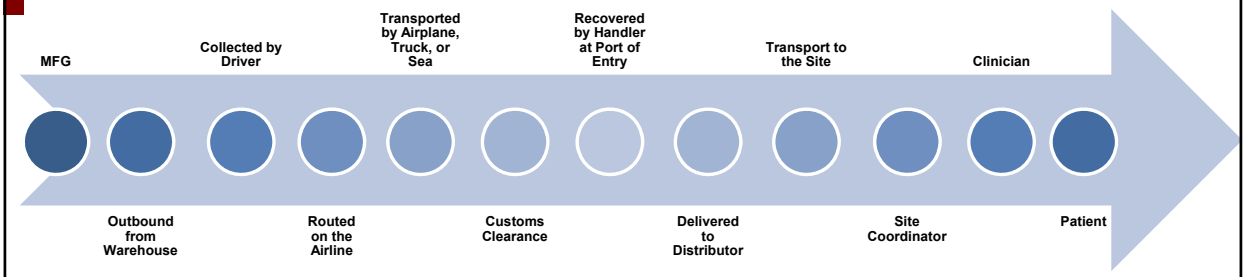
Clinical Supply Chain Management



Medical Product	Biological Material	Ancillary Materials	Packaging	Documentation	Cold Chain Management	Data
•IMP •Raw Materials •Comparator	•Blood Samples •Tissue Samples •Cells	•Diagnostics Kits •Infusion Bags •Tubing •Reagents •Delivery Devices	•Track and Trace Devices •Biohazard Bags •Seals / Zip ties	•Import/Export Certificates •Bill of Landing •Patient Information •Chain of Custody	•Temperature Controls •Storage •TT4 Monitors	•Information •Virtual •Verbal •Written

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Operational and Regulatory Landscape

Insights from Industry

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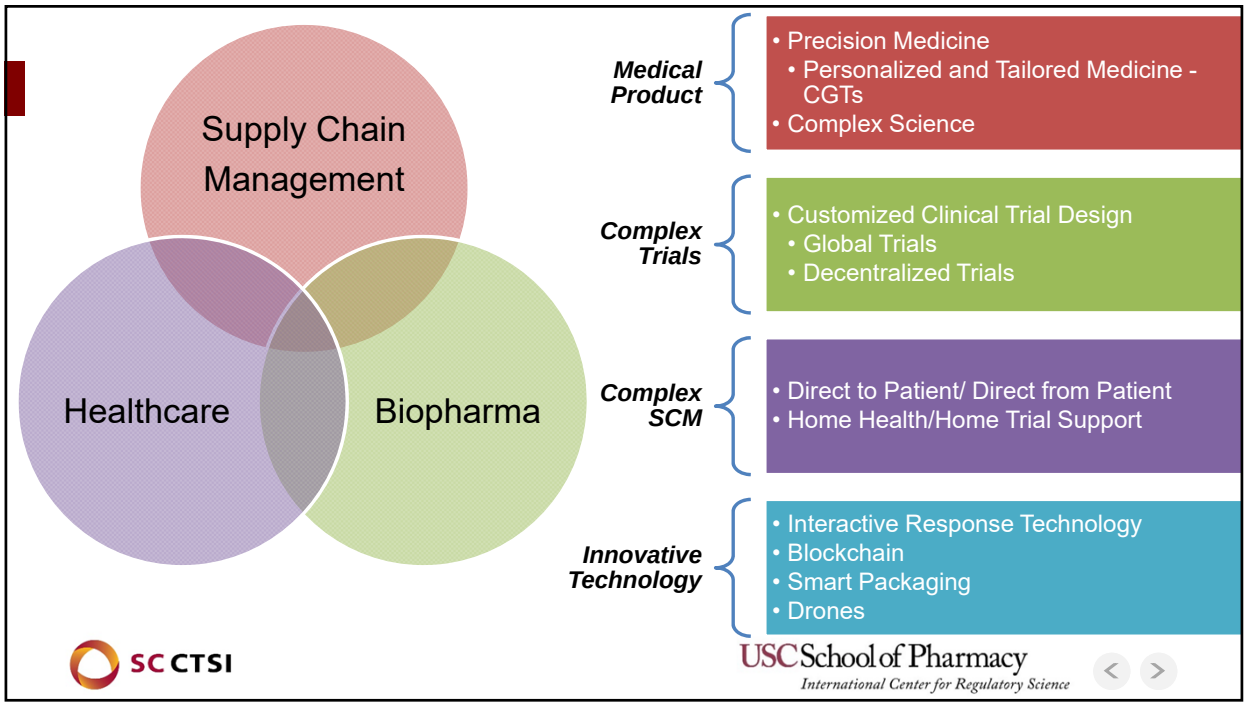
Supply Chain Management
Healthcare
Biopharma
Medical Product
• Precision Medicine
• Personalized and Tailored Medicine - CGTs
• Complex Science
Complex Trials
• Customized Clinical Trial Design
• Global Trials
• Decentralized Trials
Complex SCM
• Direct to Patient/ Direct from Patient
• Home Health/Home Trial Support
Innovative Technology
• Interactive Response Technology
• Blockchain
• Smart Packaging
• Drones
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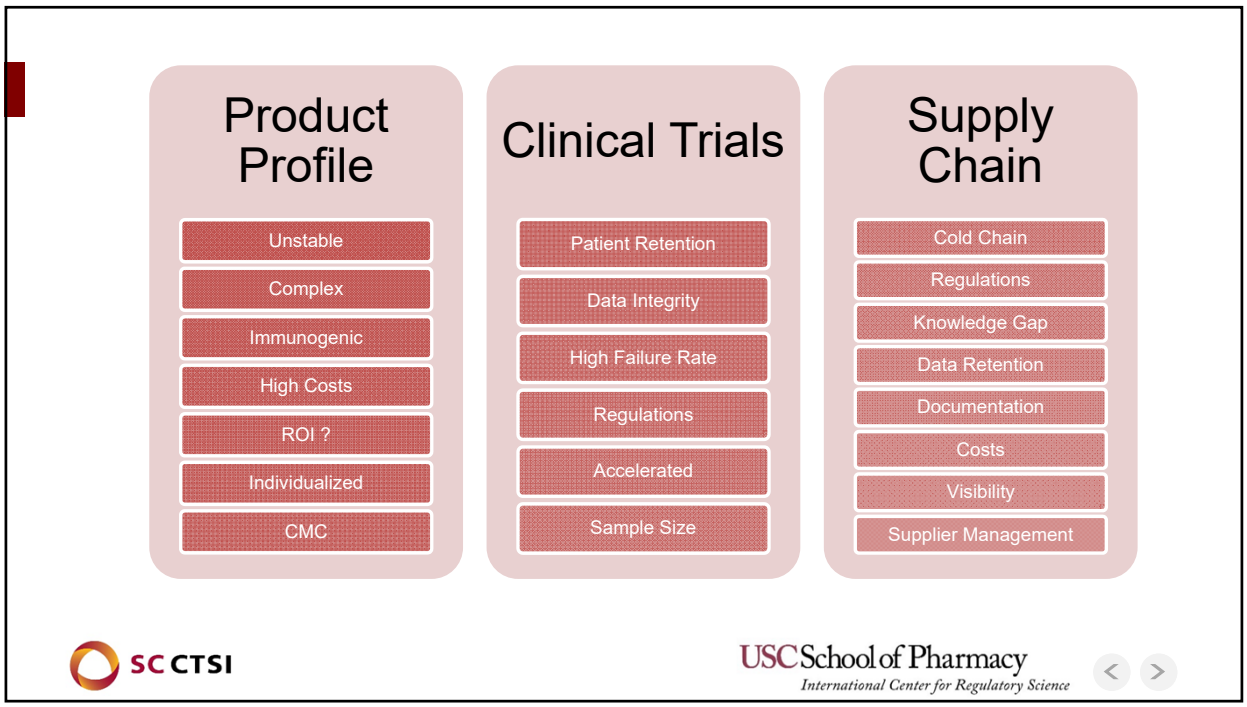
Product Profile
Unstable
Complex
Immunogenic
High Costs
ROI ?
Individualized
CMC
Clinical Trials
Patient Retention
Data Integrity
High Failure Rate
Regulations
Accelerated
Sample Size
Supply Chain
Cold Chain
Regulations
Knowledge Gap
Data Retention
Documentation
Costs
Visibility
Supplier Management
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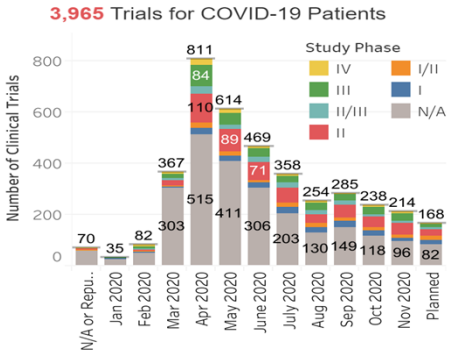
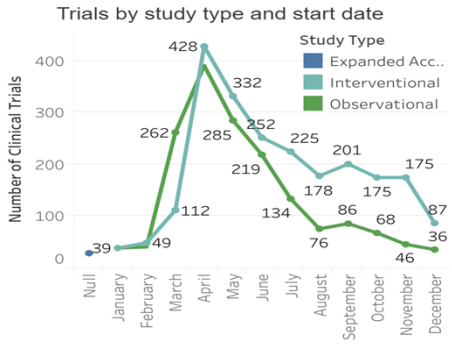
Clinical Trials – COVID-19

Trials to Treat COVID-19
Sources: CRI, CRI Analytics, Clinicaltrials.gov
Data pull December 1, 2020

CANCER RESEARCH INSTITUTE
The Anna-Maria Kellen Clinical Accelerator





https://www.cancerresearch.org/scientists/immuno-oncology-landscape/covid-19-oncology-clinical-trials

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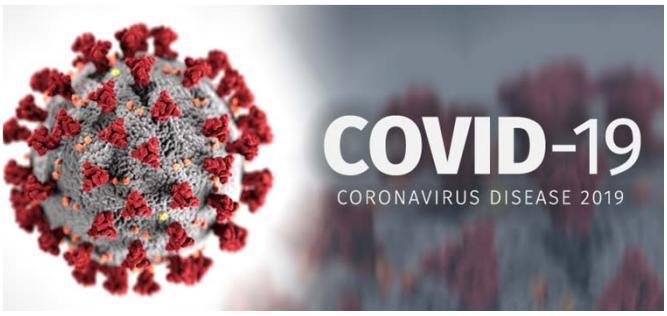
- Over 1050 Clinical Trials Halted
- Limited Access to Sites
- Patient Recruitment
- Protocol Adherence
- Availability to Supplies and Raw Material
- Staff Shortages
- Patient Care
- Supply Chain



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Lessons Learned COVID-19

- Increased Visibility to Supply Chain Gaps and Bottlenecks
- Contingency and Business Continuity
- Adaption and Innovation to Alternate Clinical Trial Models
  - GCP, ICH E6 (R3)
- Collaboration amongst Industry Stakeholders
  - Operation Warp Speed

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Career Outlook in Clinical SCM

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Roles along the Supply Chain

•Information Systems	•Warehousing	•Transportation	•Materials and Procurement
•Sales	•Vendor Management	•Customer Service	•Quality
•Regulatory (Trade Compliance)	•Operations	•Forecasting and Planning	•Packaging & Labelling

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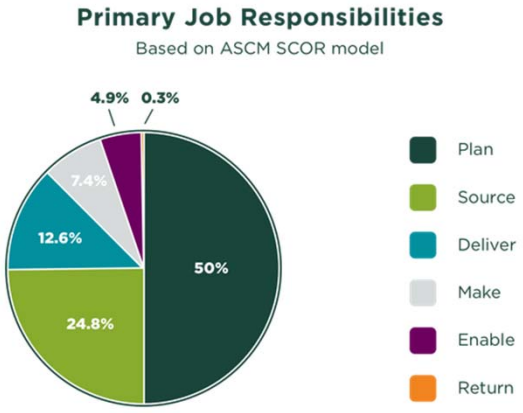
Supply Chain Responsibilities



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Career Opportunities in Clinical SCM

- There has been growth in career in Clinical Supply Chain Management
  - Over 3,000 jobs on Indeed (~500 in California)
  - Range from Associate up to VP - Level
    - Clinical Supply Chain Associate
    - Clinical Supply Chain Project Manager
    - Director/Sr. Director, Supply Chain Management

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Indeed.com
ONET.com

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Job Requirements

- Bachelors Degree
- Some years of experience with SCM
- Background can include Quality, Regulatory, Supply Chain and Business.
- Global Business Acumen
- Familiarity with GMP, GCP, and GDP regulatory requirements
- Social / Cultural / Political Awareness
- Project Management and Change Management

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Personality Traits

- Researcher
- Strategic Thinker
- Agile
- Collaborator
- Problem Solver
- Organized
- Proactive
- Negotiator
- Communicator
- Decomposer

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Salary Prospects

1. **Purchasing Agent - Median annual salary (2019):** $64,380[2]
2. **Operations Manager - Median annual salary (2019):** $100,780[2]
3. **Logistics Analyst - Median annual salary (2019):** $74,750[2]
4. **Purchasing Manager - Median annual salary (2019):** $121,110[2]
5. **Supply Chain Manager - Median annual salary (2019):** $110,630[2]
6. **Logistician - Median annual salary (2019):** $74,750[2]
7. **Logistics Manager - Median annual salary (2019):** $94,560[2]
8. **Production and Planning Clerk - Median annual salary (2019):** $48,260[2]
9. **Storage and Distribution manager - Median annual salary (2019):** $94,560[2]

https://www.rasmussen.edu/degrees/business/blog/what-can-you-do-with-supply-chain-management-degree/

[1]*Burning-Glass.com (analysis of 41,896 supply chain management degree job postings by education level, Jul. 01, 2019 – Jun. 30, 2030).*

[2]*Bureau of Labor Statistics, U.S. Department of Labor, Occupational Employment Statistics, [data accessed July 2020] www.onetonline.org.*

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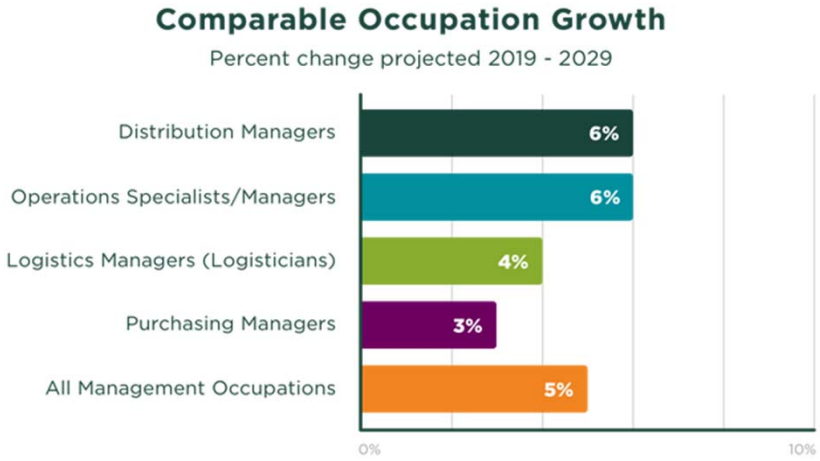
Growth in SCM



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Understanding Clinical Research Management at Academic Institutions

Zeno Ashai, MPH
Associate Director
Clinical Investigations Support Office (CISO)

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General Lifecycle of a Clinical Trial

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Main Categories of Clinical Trials done in Academia

Industry Sponsored

Pharmaceutical/ Biotech/ Medical Device Company is the Sponsor contracting with community practice/medical provider or academia to conduct the Investigation

Federally Funded

Federal entity (like NIH, NCI etc.) is the Sponsor, providing grant funding to community practice/medical provider or academia to conduct the Investigation i.e. Cooperative group

Investigator Initiated (IIT)

The same entity is both the Sponsor and the Investigator, who conceives the research, develops the protocol, as well as conducts the study.

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Successful Clinical Trial Requirement

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Contract & Budget

Task	Completed by	Federally Funded	IIT ± MultiSite	Industry
Review Protocol Calendar for Budget	Calendar Builder	✓	✓	✓
MCA Analysis	MCA Analyst	✓	✓	✓
Budget Development	Budget Specialist	Fixed Budget	✓	✓
Contract	Contract Manager	Overall Grant	✓	✓

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Regulatory Oversight

- **Regulatory Body Oversight**
  - FDA
    - Industry/Federal
    - IIT Specific:
      - IND: Drugs (CDER) and Biologics (CBER)
      - IDE: Medical Device & Radiological Health (CDRH)
      - Exempt
      - Not under FDA Oversight (i.e. prevention, epidemiology, socio & psych)
  - Institutional Review Board (IRB)
    - Local vs Central
  - Specialty Committee
    - Biosafety (Biologics i.e. live vaccine)
    - Radiation Safety (radiology/scans/radiation treatment/procedure more frequent then SOC)
- **CCC Approval Requirements**
  - Scientific Committee Review and Approval (CIC at USC)

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Regulatory Oversight (continued)

	IIT	Industry	Federally Funded
Submission to the FDA	*Site Regulatory Team*	Sponsor	Federal Agency
Submission to the IRB: LOCAL	*Site Regulatory Team*	*Site Regulatory Team*	*Site Regulatory Team*
Submission to the IRB: Central	*Site Regulatory Team*	Sponsor (main Submission) & *Site Regulatory Team (Site-Specific)*	Federal Agency (main Submission) & *Site Regulatory Team (Site-Specific)*
Bio & Radiation Safety Committee	*Site Regulatory Team*	*Site Regulatory Team*	*Site Regulatory Team*
Scientific Committee	*CIC Coordinator*	*CIC Coordinator*	*CIC Coordinator*

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Regulatory Compliance Requirements

- **GCP & CFR 21 (& ICH)**
  - Required Training and Documentation
- **SOPs**
  - Internal (Development, Implementation and Maintenance)
  - External (Protocol and Industry & Federal requirements)
- **FDA interaction**
  - Inspections
    - Routine (prior to NDA)
    - For cause
  - IIT Specific
    - Safety Reporting
    - Annual Submissions
- **Quality Assurance** (QA)
  - Routine Monitoring
    - 100% Source Data Verification (SDV)
    - Risk Based Monitoring
  - Internal Audits
  - External Industry and Federal Funding Agency Audits
    - Routine (annual, triannual)
    - For Cause
    - In Preparation for filing with FDA
- **Data and Safety Monitoring** (DSMC)
  - IIT vs Industry and Federal

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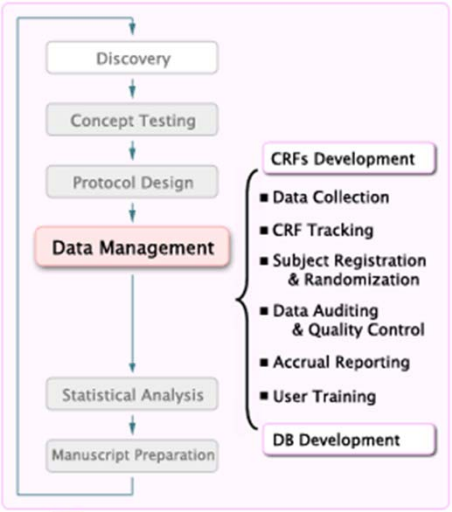
Safety Oversight: Data and Safety Monitoring Plan

	CIC		Safety & Data Monitoring		
	Main Committee	SPC	QAC	DSMC	Phase I Committee
Main Charge	PRMS with focus on science	Accrual Monitoring	Compliance, Data Accuracy & Quality	Subject Safety	Oversight of dose escalation with focus on subject safety
Activities	Initial scientific review for all studies, & amendments on IITs	Review of accrual for all active studies	Performance & review of internal audits; Review of all violations.	IIT: focus on tox profile, overall safety & any study conduct issues that may impact patient safety; Review of all SAEs	Adjudication of DLTs & decisions regarding dose escalation for IITs

Resources & Infrastructure: *Staffing*

	IIT	FF	Ind	Role & Responsibility
Protocol writer	✓			Protocol Development & Writing
Study Statistician	✓			Statistical Design & Analysis
Quality Assurance	✓	✓		Monitoring & Auditing (Internal vs External)
Regulatory Manager	✓	✓	✓	Regulatory Communication (IRB, FDA, Sponsor)
Research Coordinator	✓	✓	✓	Enrollment, Study Coordination, Source Documentation, Sponsor Communication
Data Manager	✓	✓	✓	Study Data Submission, Sponsor Communication
Specimen coordinator	✓	✓	✓	Research Specimen Processing and Shipment
Admin & Management	✓	✓	✓	Committee Coordination, Staff Supervision & Leadership
Research Pharmacist	✓	✓	✓	Oversight of study Drug Product

IIT-Specific: *Data Management*



Task	Responsible Party
Case report development (CRF)	Investigator Biostatistician Quality assurance staff
Database Built	Informatics (IT)
Data Analysis	Biostatistician Investigator
Publication	Investigator

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IIT-Specific: *Multisite Management*

Tasks	Responsible Party
CDA	USC Clinical Trial Unit, Multisite Coordinator
Site Selection	PI, Multisite Coordinator
Regulatory review & approval	PI, Multisite Coordinator
Oversight of study conduct	PI, Multisite Coordinator, DSMC, QAC
Contract & budget	USC Clinical Trial Unit

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Example of Academia Org (CISO @USC)

Regulatory Affairs Unit	Clinical research Operations Unit	Administration Business Management Unit
Regulatory Managers & Admin staff	Team Managers, Research Coordinators, Data Managers Specimen Coordinators QA managers	Business Manager
Feasibility & Protocol development, Navigation through approval process Interaction with Sponsor, & internal and external Stakeholders Maintenance of study & update of regulatory requirements	Study Execution Patient Enrollment Quality of Data & Supervision Monitoring of Study Progress Committees Support	Assistance with Budget development Interaction with Institutional Entities Review of Department Budgets Assistance with Staff hiring

Resources & Infrastructure: *Facility*

- Outpatient Clinic
- Inpatient Facility
- Infusion center
- Laboratory
- Radiology (internal / outsourced)
- Pathology (internal / outsourced)
- BMT
- Pharmacy
- Research Office Space
- Research Specimen Processing Lab
- Monitoring Room
- Medical Records Storage

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Resources & Infrastructure: *Equipment*

- Office equipment (i.e. Copier, Fax, Phone etc.)
- Software
- Lab Equipment (i.e. centrifuge, -80C Freezer, Refrigerators, Pipettes etc.)
- Data Storage (i.e. EDC cloud, eTMF)
- Electronic Clinical Trial Management System (CTMS)
- EDC (Electronic Data Capture) with capabilities for Multi-Site trials

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Thank You

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CLINICAL RESEARCH CAREER PATHWAYS

Roads to the Human Subjects Protection Program (OPRS and IRB)

Julie Slayton, Director,
Office for the Protection of Research Subjects (OPRS)
University of Southern California

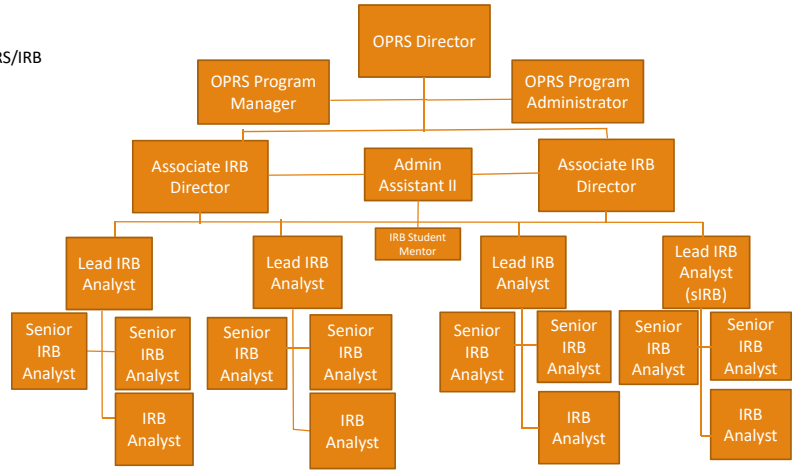
Who Am I and Why am I Here?

- Human Subjects Protection Program
- OPRS
  - Education
  - Policy and Procedures
- IRBs
  - 3 Biomedical
  - 1 Social Behavioral

Institutional Review Board (IRB)

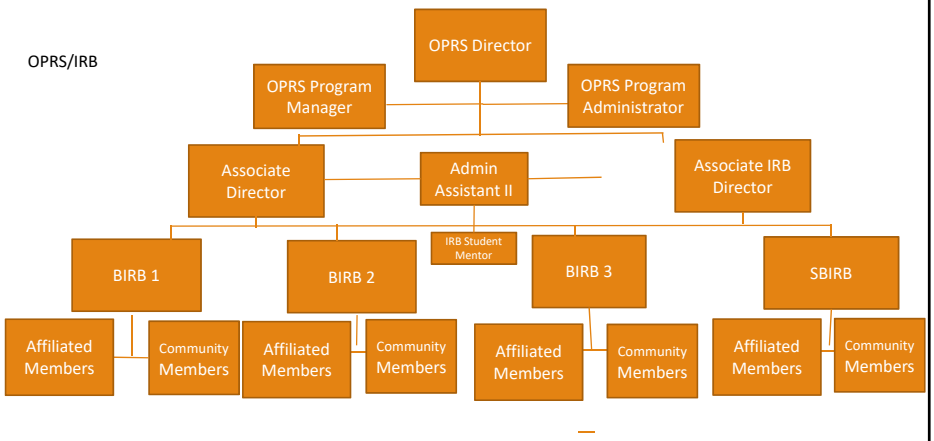
- Oversight body including standing committees that is charged with reviewing research involving human subjects
- Functions as a surrogate human subjects advocate
- IRB members can be faculty, staff, or students of the institution and local community members
- Human subjects research must be approved by the IRB before research begins

OPRS/IRB



16 Analysts

OPRS/IRB



Four Boards

Educational and Work Experiences for OPRS/IRB

- **College degree**
  - Some science experience (or not)
    - Social behavioral
    - Biomedical
  - Some research experience (or not)
    - Social behavioral
    - Biomedical
  - **Masters Degree (or not)**
    - In the sciences
    - In the arts
  - **PhD or MD (or not)**
  - **Work Experience**
    - Independent Research Experience
    - Study Coordinator
    - Volunteer on an IRB (e.g., community member)
  - **CIP (eventually preferred)**

College:

- History Major
  - Honors Thesis (data collection in Spain)
- Psychology Minor
- Spanish Literature Minor

Law School

- Course Work
  - Constitutional Law
  - Poverty Law
  - Education Law
  - Juvenile Law
- Federal OJJDP
  - Consulting with states on juvenile justice and constitutional law in schools
- Federal Clerkship
- Publishing (Harvard Constitutional Law Quarterly)

PhD

- Education Policy
- Qualitative Research
- School Funding
- Conference Presentations and Publications

LAUSD

- Researcher
  - Qualitative Research
- Director of Research
  - Oversight of qualitative and quantitative projects
  - Ethics Board
- Policymaker, member of Superintendents' Cabinets

USC

- Rossier School of Education
  - Masters of Arts in Teaching
  - EdD in Educational Leadership
- Social Behavioral IRB Member
- Social Behavioral IRB Chair
- Director of OPRS

Knocking on HR's Door: Do you have what it takes to be a CRP?

Dr. Rebecca Thomas
Dr. Elaine Fisher

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A Day in the Life of a CRP

- Oversee all study activities associated with a clinical trial
- Manage multiple projects
- Train less experience staff
- Schedule appointments, procedures, etc.
- Interact with study sponsors, monitors
- Create budgets
- Organized chaos

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Job Requirements: Minimum Qualifications

- **M**inimum = **M**ust have qualifications

Minimal Requirements

- For 2 levels of CRCs – minimum
  - → High School Diploma or GED and three years of administrative support experience
  - → Bachelor's in a health or science related field and one year of clinical research experience

Job Requirements: Preferred Qualifications

- 'Good-to-have' qualities – not required
- Benefit to you:
  - May lead to higher level of success in getting to the interview
- Benefit to the organization:
  - Assists the HR recruiter & search committee narrow down a big applicant pool and select top candidates.

Example: Minimum vs Preferred Qualifications

Minimum	Preferred
Bachelor's degree	Master's degree
Ability to manage confidential & sensitive information.	Bilingual in English & Spanish
	History of working with vulnerable populations

How to get a job with no qualifications or experiences?

- **DON'T** oversell
- **DO**
  - Identify your skill set and gaps
  - Be realistic
  - Network
  - Volunteer

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Leveled Positions

- **CRC 1 (entry level)** – Responsible for administrative activities associated with the conduct of clinical trials. Completes source documents/case report forms and performs data entry. Maintains and stores research data. Assists with participant scheduling.
- **CRC 2 (entry level)** – Manages research project databases, developments study related documents, and completes source documents/case report forms. Interfaces with research participants and study sponsors. Determines eligibility and consents study participants according to protocol.
- **CRC 3 (intermediate level)** - Independently manages significant and key aspects of a large clinical trial or all aspects of one or more small trials, or research projects. Trains and provides guidance to less experienced staff. Interfaces with research participants and resolves issues related to study protocol(s). Interacts with study sponsors, monitors and reports SAEs. Resolves study queries. Provides leadership in determining, recommending, and implementing improvements to policies and procedures. Monitors IRB submissions.
- **CRC IV (advanced level)** – Functions as a team lead to recruit, orient, and supervise research staff. Independently manages the most complex research administration activities associated with the conduct of clinical trials. Determines effective strategies for promoting/recruiting/retaining research participants. Responds to requests and questions throughout the life cycle of the study.

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Clinical Research Coordinators: Transferrable Skills

- Associated with entry level positions
- Internet-available resume templates focused on generalities
- Academic Preparation
  - Technical diplomas/certificates
  - Degrees in health-related fields
- Clinical Setting & Clinical Roles

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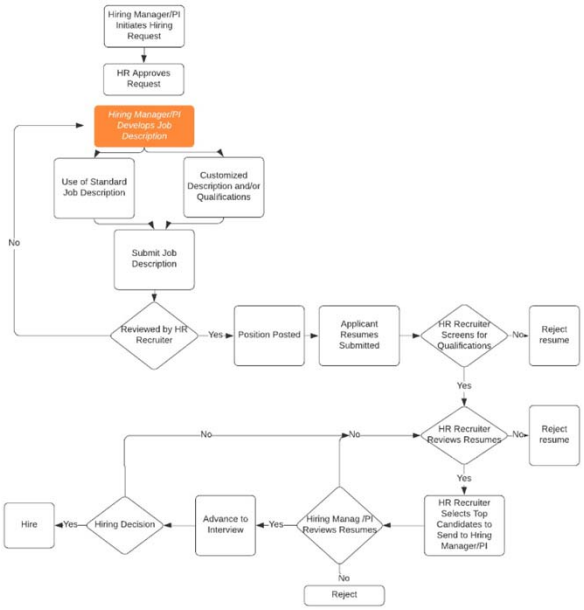
Hiring Process



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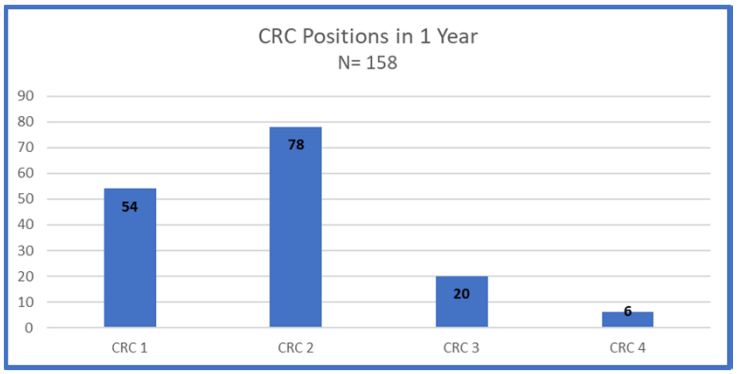
HR Process: A view from the HR Recruiter Seat



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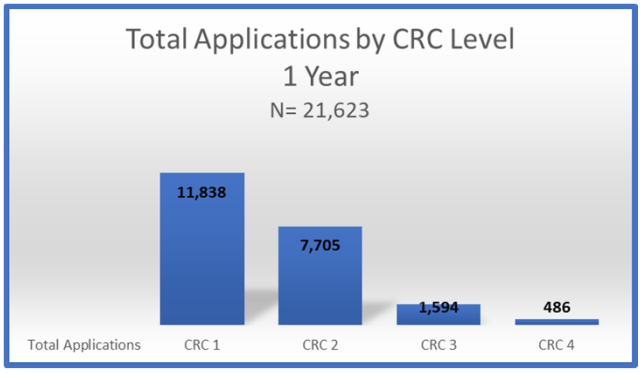
Total Applications Received



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Number of Applications/Job for CRC 1-4				
	CRC 1	CRC 2	CRC 3	CRC 4
Mean± SD	160±95	99±72	80±56	81±40
Median	168	91	69	80
Range	1-331	1-256	2-209	45-154

Number of Days to Fill a Position N = 158				
	CRC 1	CRC 2	CRC 3	CRC 4
Mean± SD	55±45	56±45	75±66	56±43
Range	4-222	1-292	14-259	36-128

What Hiring Managers Want

"Accurate matching the candidate to the project needs leading to rapid project initiation without excess training."

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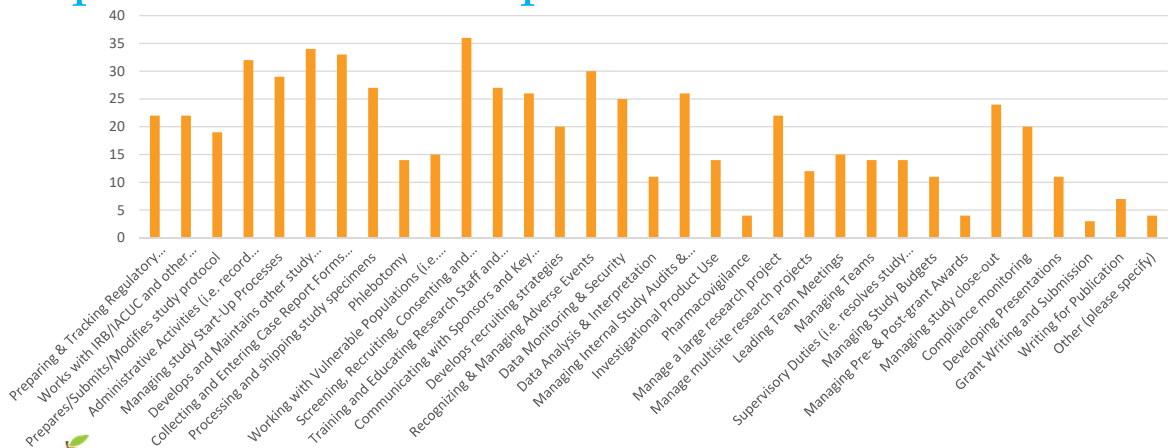
Check all tasks/competencies considered important for a CRC position



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Top 5 Ranked Tasks/Competencies for a CRC Position

1. Administrative Activities (95%)
2. Screening, Recruiting, Consenting, and Educating Study Subjects (89%)
3. Develops & Maintains Study Related Documents (89%)
4. Collecting and Entering Case Report Forms (ECRF's) (84%)
5. Recognizing and Managing Adverse Events (65%)

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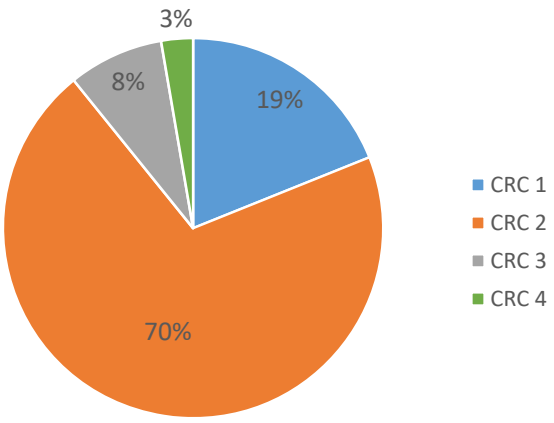
CRC Level: Last Hire



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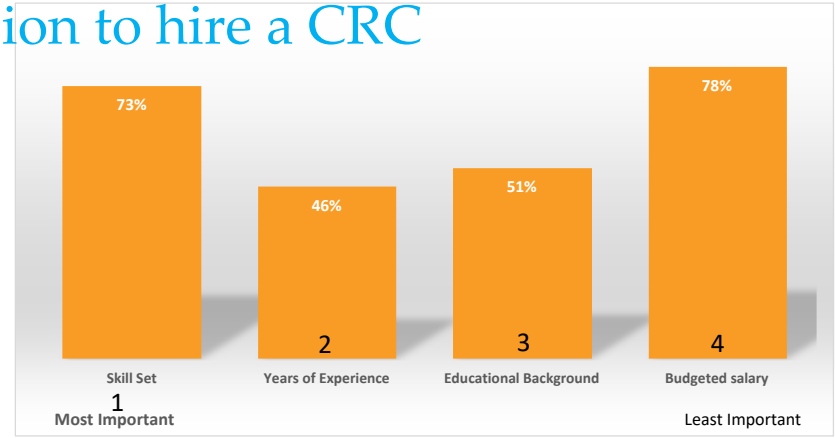
Rank order of factors influencing the decision to hire a CRC



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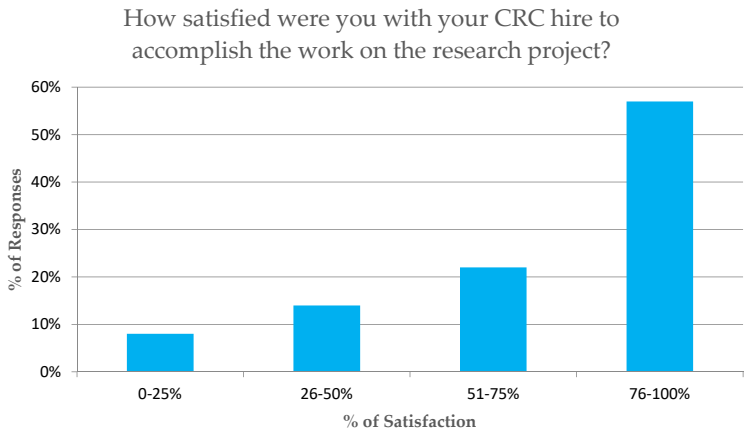
Satisfaction of Last CRC Hire

"I initially targeted a CRC1 and that was too inadequate of a skill set." - 76 - 100%

"She had 10 years of experience but needs more hand-holding than I had hoped" - 51 - 75%



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Summary

- 89% of hires were for entry-level CRC I & II positions
- There is a commonality of tasks/competencies selected as top 5 requirements, but no pattern emerged for the type of tasks/competencies required by CRC level.
- 22% of PIs/Hiring Managers rated 50% or lower overall satisfaction with the hire, and approximately 16% of respondents would not hire the individual again.
- While budget was ranked 4th when hiring for a CRC position, comments by PI's/Hiring Managers may indicate a lower level CRC hire may have been inadequate to meet project needs.

Leveraging your value

- How to make your resume stand out
  - Include relevant employment & academic dates – month/year
  - Highlight experience
    - Clinical roles – direct and indirect
    - Clinical research – scope, roles & responsibilities on projects, e.g., opening & closing out, recruitment, regulatory considerations, etc.
    - Areas of expertise in disease specialties, i.e., oncology, CV, infectious disease
    - Clinical skill set – phlebotomy, processing samples, etc.
    - Experience with electronic data capturing systems (EDC)
    - Certifications – from professional organizations (ACRP, CCRP)
    - Trainings – certificates & badges

Retention Strategies

- Onboarding – Strong training component
- Mentoring
- Resiliency: Managing stress & burnout
- Recognition
- Career pathway
- Ongoing education – self-development

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Managing Your Career

- Manage your career

  "No one cares more about your career than you."

- Resources
  - Translational Workforce Development (TWD) ***Free*** Course Catalog
    - USC collaboration SC CTSI

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  - **COMING SOON STELLAR** – Career navigation

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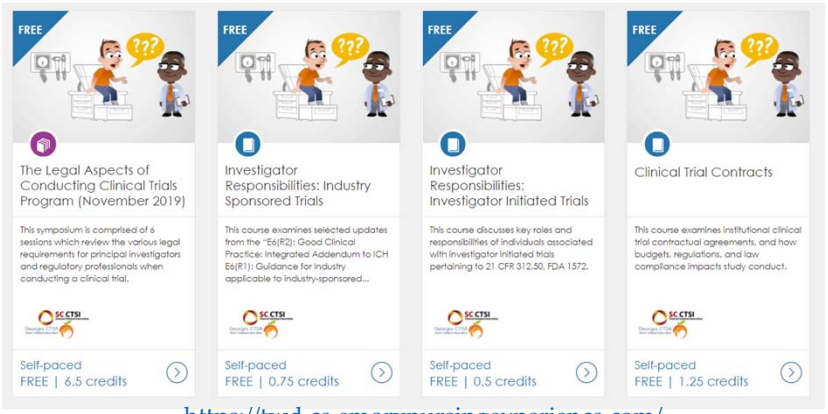
Translational Workforce Development (TWD) Course Catalog



Certificates & Badges

https://twd.ce.emorynursingexperience.com/

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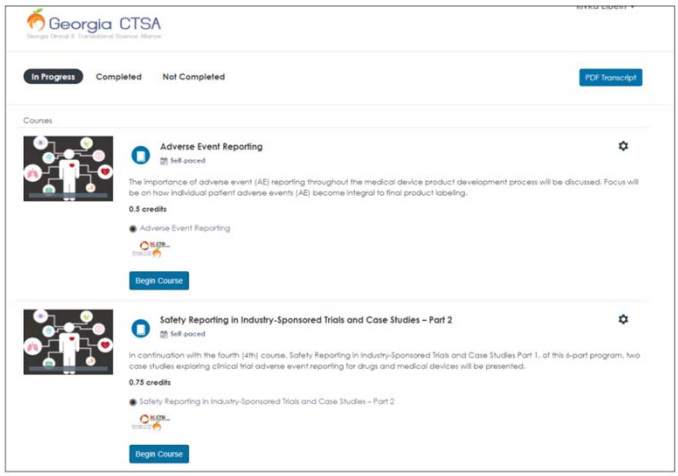
Dashboard Tracking: Pick up where you left off



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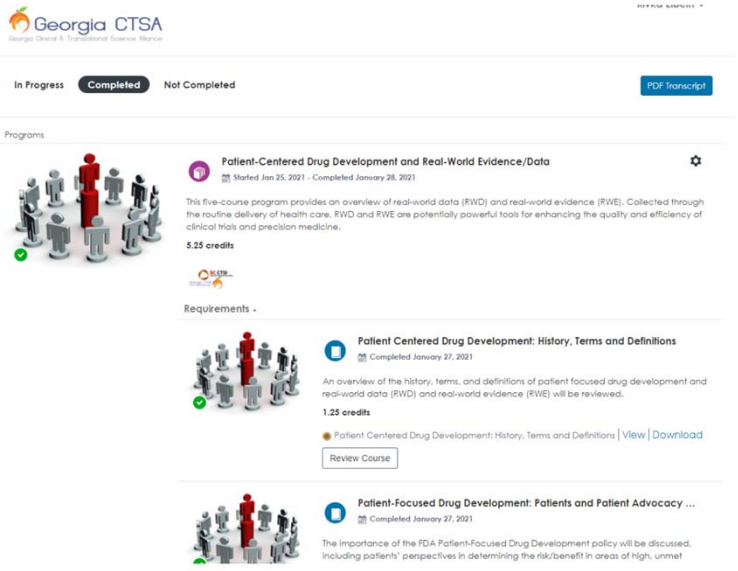
Monitor courses & programs completed



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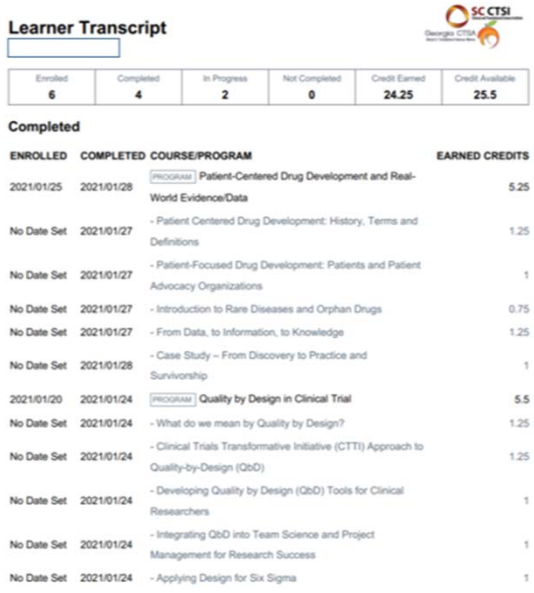
Print a transcript



Learner Transcript

Enrolled	Completed	In Progress	Not Completed	Credit Earned	Credit Available
6	4	2	0	24.25	25.5

Completed

ENROLLED	COMPLETED	COURSE/PROGRAM	EARNED CREDITS
2021/01/25	2021/01/28	PROGRAM Patient-Centered Drug Development and Real-World Evidence/Data	5.25
No Date Set	2021/01/27	- Patient Centered Drug Development: History, Terms and Definitions	1.25
No Date Set	2021/01/27	- Patient-Focused Drug Development: Patients and Patient Advocacy Organizations	1
No Date Set	2021/01/27	- Introduction to Rare Diseases and Orphan Drugs	0.75
No Date Set	2021/01/27	- From Data, to Information, to Knowledge	1.25
No Date Set	2021/01/28	- Case Study – From Discovery to Practice and Survivorship	1
2021/01/20	2021/01/24	PROGRAM Quality by Design in Clinical Trial	5.5
No Date Set	2021/01/24	- What do we mean by Quality by Design?	1.25
No Date Set	2021/01/24	- Clinical Trials Transformative Initiative (CTTI) Approach to Quality-by-Design (QbD)	1.25
No Date Set	2021/01/24	- Developing Quality by Design (QbD) Tools for Clinical Researchers	1
No Date Set	2021/01/24	- Integrating QbD into Team Science and Project Management for Research Success	1
No Date Set	2021/01/24	- Applying Design for Six Sigma	1

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Other Resources

- CLIC
- Diamond
- National Institute of Health
- International Association of Clinical Research Nurses (IACRN)
- Association of Clinical Research Professionals and SOCRA

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Regulatory Science Virtual Symposium

Clinical Research Career Pathways

Wrap-Up!

Eunjoo Pacifici, PharmD, PhD
Chair and Associate Professor, Regulatory and Quality Sciences
Associate Director, DK Kim International Center for Regulatory Science

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Resources

Presented by the USC School of Pharmacy International Center for Regulatory Science and the Southern California Clinical and Translational Science Institute

This certifies that

You should have received the link to take the program evaluation.

Follow this link to the Survey:
Take the Survey

Please complete the program evaluation to receive a certificate of completion by Friday, March 19, 2021.

Eunjoo Pacifici, PharmD, PhD
Director
International Center for Regulatory Science

Thomas A. Buchanan, MD
Director
Southern California Clinical and Translational Science Institute

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Regulatory Science Virtual Symposium

Save the Date!

Principles of Global Clinical Research for Medical Devices

Friday, April 9, 2021
9am-3pm PST

Virtual Symposium
Hosted Online via Zoom

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Clinical Workforce

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Brought to you by the University of Southern California Department of Regulatory and Quality Sciences and SC-CTSI, these self-study modules allow you to learn and familiarize yourself with the concepts of monitoring and auditing of clinical research.

To access this free resource:

1. Go to: http://uscregsci.remote-learner.net
2. Create a new account
3. Open your email and confirm account
4. Select the module and click "Enroll Me"

MODULE 1: MONITORING

- Quizzes
- Templates
- Checklists
- SOPs
- Resources

MODULE 2: AUDITING

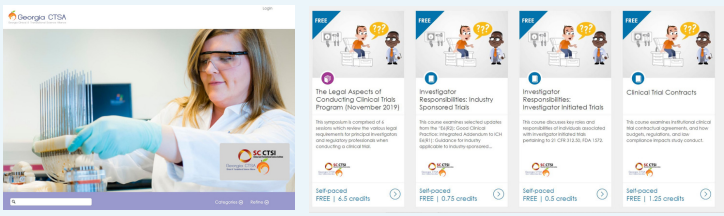
Coming soon!

GEORGIA CTSA & SC CTSI: ONLINE COURSE CATALOG

Brought to you by collaborative efforts of Georgia CTSA and SC CTSI, these online courses and programs are geared toward clinical research professionals at every stage of their professional development.

- Earn a certifcate or badge with contact hours upon completion of course or program
- Contact hours for CRP certification renewal

To access this free resource:
https://twd.ce.emorynursingexperience.com/



USC School of Pharmacy
Department of Regulatory and Quality Sciences

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Georgia CTSA
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