Funding Research

Statement of Problem

On April 5, 2014 the Leadership for Innovation in Team Science (LITeS) Cohort presented a report titled "Promoting Team Science at the University of Colorado Denver." The general challenge addressed by the four teams comprising the Cohort was to generate new approaches and recommendations for enhancing the quality and volume of team science activities on our campus. The report addressed issues such as Education and Training, Funding, Space and Physical Environment, and Toolkits needed to promote team science.

In the Funding Team Science section of the report, one of the LITeS Teams explored alternative funding strategies and approaches to support team science. Reducing inefficiencies, improving and promoting the medical campus image, bolstering philanthropy and developing innovative funding mechanisms were all identified as areas of opportunity. Since that report was published, progress has been made in many of the areas identified, including, but not limited to:

- A new Director for the Office of Grants and Contracts has been hired and is tasked with improving efficiencies and processes to make the University more competitive. A new Director for the Technology Transfer Office (TTO) at the Anschutz campus has also been recruited.
- A complete overhaul of the Development Office (now called Advancement) both at the CU System level and at the Anschutz Medical Campus is underway and new leadership has been hired to bolster philanthropy.
- CU contracted with McKinsey and Company, a highly respected consulting group and published a report (January 2014) titled "Enhance the Operational Excellence and Diversification of Funding for the CU Research Enterprise." The report provides a blueprint on how CU could diversify and grow research funding. An Executive Director was hired to implement the blueprint created from the McKinsey report.

In addition, two external reports have been published that highlight the need for the University of Colorado/Anschutz Medical Campus to press on in its quest to diversify research funding and demonstrate operational excellence. One of these reports, "The Rise of Innovation Districts: A New Geography on Innovation in America," was published by the Brookings Institute, and the other was published in the May 2014 issue of Nature Biotechnology called "Surveying the best in translation; how to build powerful translational research centers."

Going forward, the charge to the 2015 LITeS team has been to operationalize elements of previous reports so as to maximize process efficiency and revenue potential for the University of Colorado AMC. Our focus has been on the area of clinical trials operations and specifically how to structure a clinical trials office to best support two key constituencies – 1) investigators at the University of Colorado, and 2) external partners desiring to engage in clinical trials at UCD. From the perspective of both groups, the process of obtaining approval to conduct clinical trials is exceptionally complicated and slow. Our general hypothesis is that the process required to perform a clinical trial at the University of Colorado Denver can be

dramatically improved (i.e. simplified and expedited) and that this will result in significant benefits in terms of our overall academic mission, attracting the most exciting new medical therapies, and increased revenue to the University.

The process

The LITeS team has met regularly during the course of the past academic year to facilitate ongoing discussions and investigation of appropriate processes. Interviews have been conducted with:

Internal:

1) Steve Van Nurden – President and CEO, Fitzsimons Redevelopment Authority
2) Jean Kutner – Chief Medical Officer
3) Amy Gant – Director, Office of Grants and Contracts
4) Alison Laken – Director, Regulatory Affairs
5) Tom Flaig – Director of Clinical Research, UCD Cancer Center
6) Colleen Kellackey – Director, Clinical Trials Office, UCD Cancer Center
7) Derek Schatz – Supervisor, Hematologic Malignancies Trials, UCD

External:

1) Elizabeth Anderson – Director Oregon Health Sciences University Cancer Clinical Research Core
2) Ralph Gonzalez, M.D., MSPH – Chief Innovations Officer, Associate Chair for Ambulatory Care and Clinical Innovation for the Department of Medicine, UCSF
3) John Bennett, Associate Vice Chancellor for Innovation Initiatives, UCD

To gain a better understanding of the current infrastructure for conducting clinical trials on campus, we carefully reviewed the Deloitte and McKinsey reports and recommendations provided to us by our project sponsor Don Elliman and several process maps provided by staff involved in the clinical trials process at AMC.

The proposal

The general concept proposed by both the Deloitte and McKinsey reports is that organization and centralization of clinical trials infrastructure is a key step towards improving overall competitiveness for UCD. While we agree with this in theory, we believe that the specific design and structure of a central clinical office is critical to optimal operational success. Specifically, certain components clearly should be combined to improve speed and efficiency, while other aspects of the clinical trials machinery should remain as stand-alone operations. Details are shown in Figure 1. We propose creation of a UCD Office of Clinical Research (OCR). The clinical trials services offered by this office would represent “one stop shopping” for both internal and external partners seeking to open clinical trials at AMC. Such components would include:

- Grants and contracts negotiations
- IRB submission
- Technology Transfer
- Regulatory Affairs

To coordinate these functions, we propose creation of a position – Director of Clinical Research (DCR). As outlined in Appendix A, this individual would be primarily responsible for creating the fastest and most efficient process possible for approving clinical trials. Aside from the areas listed above, the DCR would also serve as a key liaison with UCH.

We propose that the OCR be closely allied with the UCH Chief Scientific Officer (CSO), a position currently being developed at AMC (see appendix B for recommended qualifications).

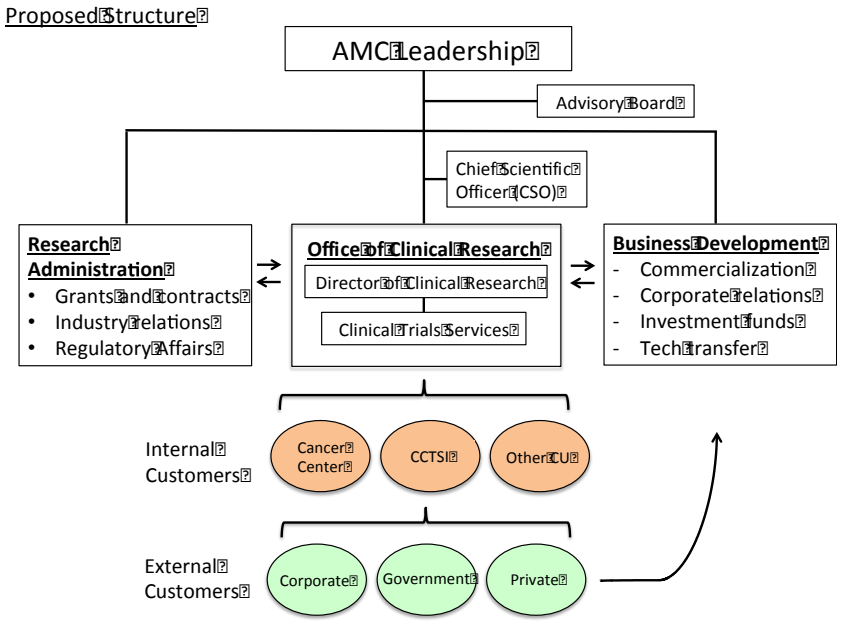

Figure 1: Schematic overview of the Office of Clinical Research and key partnerships and organizational structure.

Another structural component to the overall OCR structure should be the creation of an advisory board. As described in Appendix C, the board would be comprised of key stakeholders in the clinical trials process, as well as various types of expertise. The role of the board would be to review the OCR process on a regular basis, establish and monitor metrics for success, and make recommendations to the EVP for ongoing process improvement.

As a further structural feature, we propose that OCR be closely allied with Business Development functions at AMC. The primary issues with regard to business development are corporate relations, the commercialization of UCD intellectual property, and the development of investment funds. While these functions have typically resided within the technology transfer realm, we suggest that further development and specialization in these areas is likely of great benefit and should function in collaboration with the OCR. Business Development would also serve as the central portal for external partners who do not have pre-existing relationships with disease specific teams. Inclusive of this relationship would be regular discussions between the CSO and Associate Vice Chancellor for Innovation Initiatives. This would serve as a springboard to connect recent initiatives through UCD including In Works, and STRIDE, a new health care technology campus located in downtown Denver, to

collaboratively create meaningful solutions to health care problems and infrastructure as well as provide a springboard for ideas incubation and entrepreneurship.

As shown in Figure 1, each of the major clinical operations on campus (CCTSI, Cancer Center, etc) would maintain disease specific operations consisting of individuals who have initial contact with both investigators and external parties. Proposed trials would be begin using a standardized template (prepared by the OCR), which would be submitted to OCR via a central web-based portal. Subsequent interactions with the UCH Research Studies Office and the appropriate IRB would be managed by OCR, in collaboration with disease teams.

In order to be competitive in the clinical trials marketplace, speed and efficiency are critical. We propose that an initial target of 60 days be the goal, measured from the time a proposal is submitted to OCR to the time the trial is approved to begin. While achieving this goal would be an enormous improvement in the current process, we note that privately managed clinical research organizations can often achieve much faster turn-around times (on the order of 30 days). Consequently, continuing to streamline and improve the approval process is likely to be an ongoing effort for some time to come.

Alternatives and Related Opportunities

Throughout our discussions, we considered the option of contracting out industry-sponsored trials to external organizations such as CROs but the general consensus was that this would not be a cost-effective alternative. However, we would be supportive of a “hybrid” model in which management of select trials may be contracted out on a per-need basis.

Another recommendation we favor further developing the position and scope of responsibilities for a Chief Innovations Officer. Please see Appendix D for details.

Appendix A

Position Description – Director, Clinical Research Operations

Job Summary:
The Director, Clinical Research Operations is a key position within the Office of Clinical Research that is responsible for developing and overseeing all phases of clinical research, including observational and real-world research studies as well as patient registries. This role will advance the operations and business practices for studies, significantly evolve the organization's infrastructure and capacity to conduct national, multi-site clinical trials and ensure that research is conducted in accordance with all governing laws, regulations and ethical standards. This position will have key relationships internally with clinical project teams, marketing, business development, as well as administration and externally with regulatory bodies, external service providers and some aspects of client engagement.

Requirements:

- Minimum requirements:
  - Master's degree in healthcare or business administration (e.g. MSN, MBA, MHA, MPH)
  - Minimum 5 years of experience designing, leading and or managing clinical trials (or clinical trial teams), observational or real-world research or patient registries
  - Industry experience (Biopharma, CRO, ARO or large site network)
  - Strong interpersonal and communication skills; must interact effectively with physicians, families, visitors, as well as executive and medical leadership
  - Demonstrated business skills and management experience
  - Leadership abilities; must be able to direct the efforts of diverse teams to achieve business goals and objectives
- Preferred:
  - Doctorate (PhD, PharmD, DBA, etc…)
  - 10 years progressively-responsible work experience in a management role affiliated with clinical or real-world research
  - Recent cGCP formal training
  - Detailed understanding of data extraction from clinical and research systems or databases

Essential Job Functions:

- Line management of all existing projects. Ensure that studies proceed according to timelines including (as necessary) IRB submission, study initiation and progression, data collection and reporting as well as study closeout activities. Serve as a point of contact for principal investigators, study coordinators and sponsors and/or research clients.
- Integrate the research and commercial aspects of diverse clinical research studies to ensure quality, metric-driven, value-creating research either by overseeing a team of research professionals or by supporting a research team.
- Develop new programs, approaches and methods to recruit and retain study participants. Facilitate the development and implementation of standard operation

procedures, including a quality assurance program and occupational health and safety guidelines appropriate to staff, students and study subjects.

- Ensure regulatory compliance; serve as the senior operations representative during regulatory compliance audits.
- Identify and make recommendations regarding emerging technologies and their potential application to existing and future clinical trials.
- Assist in the development and implementation of IT, research data management, and business intelligence systems.
- Support the identification, evaluation, development and delivery of new services and operational capabilities to reflect investigator interests, institutional goals, sponsor needs, industry standards and the evolving scientific landscape.
- Assist with professional education programs to train and mentor study coordinators and junior investigators on how to conduct ethical and effective clinical research studies.
- Assist in the preparation of business and grant budgets, including operating expenses and capital expenditures; oversee administration of invoicing and collection for all projects.
- Determine the appropriate pricing strategies and develop pricing models to analyze the financial results of various types of research activities. Make recommendations regarding the appropriate mix of research endeavors needed to achieve a balanced portfolio to meet both academic and financial goals.
- Monitor sponsor and investigator satisfaction with metric-driven approaches. Cultivate ongoing relationships with sponsors and investigators to secure repeated new business opportunities.
- Liaise with all parties involved in conduct of research. This includes but is not limited to researchers, clinicians, healthcare leaders, FDA, support staff and industry sponsors of research to manage research activities and facilitate timely communications.
- Develop a centralized structure and processes to oversee research applications, budgets, billing and compliance with federal regulations.
- Oversee development or implementation of education and training programs for staff and physicians involved in research. These include federal regulations, and approved policies and standard financial management, protection of human subjects, the research cycle; internal and eternal audits that promote ethical conduct in research.
- Facilitate relationships with internal & external research clients to foster expanded opportunities for collaboration and/or participation in revenue-generating research studies.

Appendix B

Position Description: Chief Scientific Officer (CSO)

Background: The Chief Scientific Officer (CSO) is an executive leadership position in the Office of Clinical Research within the UC academic health system.

Responsibilities

The primary responsibility of the CSO will be to lead the research operation of the Office of Clinical Research within the UCHealth System and assure that it provides an efficient and desirable environment in which to conduct clinical research while ensuring compliance with federal and regulatory requirements. The ultimate goal is to create the infrastructure, processes, informatics and analytics to function as a learning health care system, with real-time integration of data, research, learning and clinical care. The CSO will be responsible for establishing and executing a strategy within UC Health for conducting research, accelerating new scientific discoveries and integrating the research and clinical missions. The CSO will identify and facilitate strategic opportunities for leveraging clinical and research programmatic growth and excellence. The CSO will oversee the scientific functions of UC Health, combining knowledge of research conduct with leadership and business skills to promote efficient and compliant conduct of high quality research within and by UC Health. The CSO will advise UC Health's executive leadership and Board in scientific matters. The CSO will be responsible for establishing close working relationships with key research partners, including University of Colorado Research Administration, potential funders, sponsors and donors, and, especially, investigators. The CSO will have oversight of research policies, procedures and activities, ensuring that all research is conducted according to federal and other regulatory standards (e.g. FDA Good Clinical Practice (GCP), International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), Office for Human Research Protections (OHRP), Joint Commission, Centers for Medicaid and Medicare Services (CMS), Association for the Accreditation of Human Research Protection Programs (AAHRP), etc).

Chairs

- RAMP
- Research Governance Committee (newly formed; includes both UCD and UCHS)

Serves on:

- SEG

Key Partners

- University of Colorado Research Administration: Vice Chancellor for Research (Richard Traystman), Assistant Vice Chancellor for Regulatory Compliance (Alison Lakin), Director of Office of Grants and Contracts (Amy Gannon), Vice Chancellor for Clinical and Translational Science (Ron Sokol)
- UC Health Chief Financial Officer
- Director, University of Colorado Cancer Center
- UCHS Chief Medical Officers
- UC Health IRB (for North and South)
- UC Health Chief Information Officer

Accountability [see draft Office of Clinical Research Organizational Chart dated 2/13/15]

Directly accountable to:
Research Governing Committee
UCHA CMO and UCHA CEO

Direct reports to this position:
Director and staff of UC Health Office of Research Support Services (RSS)

Qualifications

- Doctoral-level degree, such as a Doctor of Philosophy (Ph.D.) and/or Doctor of Medicine (M.D.)
- Distinguished record of research leadership, including experience building a successful research program and a record of scientific contribution in a focused area of clinical research, exemplified by peer-reviewed publications, extramural funding and overall stature in a field of study.

Desired characteristics

- Strong results-driven leadership skills
- Strong networking skills with experts in academia & industry: solid record of maintaining and developing successful relationships with opinion leaders and investigators in diverse disciplines
- Strong ability to handle multiple programs and portfolios
- Strong conceptual thinking and innovative skills and ability integrate input from diverse fields of research
- Excellent interpersonal skills with the ability to interact with physicians, nurses and researchers across the health system.
- Strong communication and public presentation skills
- Maturity in managing a individuals in a collaborative environment and in matrix team structure
- Excellent judgmental, decision-making and consensus-building capabilities
- Sound judgment and a creative manner of approaching issues and devising sound solutions based on thorough research, information analysis, and collaboration
- Results-oriented, energetic, and agile
- Flexibility to acquire additional competencies and skill sets as mandated by the changing needs of the organization
- Well organized and highly detail oriented, able to take initiative, work independently, and follow through meticulously and to work well with an interdisciplinary team and in collaboration with other institutions.

Appendix C

OCR Advisory Board

Charter

The role of the Advisory Board to the Office of Clinical Research (OCR) is to oversee the academic, scientific, financial, strategic, and operational performance of clinical research efforts coordinated by the OCR. The Advisory Board is comprised of members representing campus leadership and infrastructure, research centers on campus, as well as disease/specialty clusters that conduct a large number of clinical trials. The representation on the Advisory Board was modeled after a successful academic organization that performs a large number of industry-sponsored clinical trials, the Duke Clinical Research Institute (DCRI). It is important to note that the number of clinical trials may vary significantly over time within the various departments, thus representation on the Advisory Board designated as 'disease/specialty clusters' will also vary in concert with this fluctuation. The current recommendation is based on information obtained from Alison Lakin on which disease/specialty areas perform the majority of clinical trials on the University of Colorado Anschutz Medical Campus at this time. Another note is that we have attempted to be comprehensive in representation to get feedback from all potential stakeholders (for example, Center for Personalized Medicine does not at this time conduct any clinical trials but may be an important stakeholder in the near future). Our vision is that the new Director of Clinical Research (DCR) will finalize the composition and membership of the Advisory Board and that our recommendation is only a suggestion.

The Advisory Board will meet monthly and the term of the membership on the Advisory Board will be 3 years. Specific duties of the Advisory Board include evaluating OCR effectiveness, offering advice for quality improvement, serving as an advocate for the OCR, assessing needs by stakeholders (clinicians, researchers, hospital and industry), and providing guidance on strategic directions.

Advisory Board Membership/Interactions Recommendations

VC for Research
CCTSI/ DOM Vice Chair of Clinical Research
Business Development
Central OIT
COMPASS
Associate VC for Innovation Initiatives
CU Foundation
CCTSI
Cancer Center
Wellness Center
Center for Personalized Medicine
Accords
Barbara Davis Center
Colorado Prevention Center
Children's Hospital Colorado

Stakeholders

Centers

Cancer Center
CCTSI
Barbara Davis Center
Wellness Center
Center for Personalized Medicine
ACCORDS/COHO

Schools/Colleges

Medicine
Pharmacy
Dental Medicine
Nursing
Public Health

Hospitals

UCH
Children's Hospital Colorado
VA
Denver Health

University Leadership and Organizations

Vice Chancellor for Research
Vice President for Health Affairs
Chancellor for the University of Colorado Anschutz Medical Campus
Associate VC for Innovation Initiatives
CU Foundation

Departments/Divisions with Frequent Clinical Trials

Gastroenterology and Hepatology
Infectious Disease
Endocrinology
Renal Diseases and Hypertension
Endocrinology, Metabolism and Diabetes
Neurology
Surgery

Infrastructure

Office of the Vice Chancellor for Administration and Finance
Office of Regulatory Compliance
Office of Grants and Contracts
Technology Transfer Office
Office of Information Technology
COMPASS (databases)
Project Management

Appendix D

Office of Innovations and Entrepreneurship

Background: The Chief Innovations Officer would hold an executive leadership position in the Office of Clinical Research within the UC academic health system. Currently, John Bennett has been appointed by Don Elliman and holds the position of Associate Vice Chancellor for Innovation Initiatives with connections to both the UCD and Anschutz campuses. He currently reports to Provost Rod Nairn.

Mission: To foster and facilitate innovative ideas that require leadership and nurturing support**.** Through educational initiatives such as In Works, a new program of the University of Colorado Denver and the Anschutz Medical Campus, the purpose and mission is to bring "together faculty, staff and students from across the two campuses, as well as entrepreneurs and leaders from industry, government, education and the community, to address problems of importance to human society." To this end, the CIO would interact closely with the CSO as well as the CQO to build partnerships across health care systems, foster and develop pathways for taking creative ideas for improving health care for patients to fruition through investments and venture capital funding. This might include monthly forums with the offices of TT and GC, the CSO, as well as off campus biotechnology entrepreneurs to explore and discuss new ways to improve the science and business opportunities within the associated campuses. Creating a Center of Innovation that would work with or be housed together within the Business Development Center or potentially within the newly formed STRIDE initiative, a health technology campus, based in downtown Denver, "dedicated to enabling healthcare innovation by focusing on: digital health, wearable tech, "smart" device, and enterprise platforms." This campus would interact as well with the Biosciences Park located on the Anschutz Medical campus and act as a catalyst in assisting various departments and individuals in creating offshoot CROs and start up companies. Creating educational opportunities for faculty, including support of mini-sabbaticals within industry, partnering with the UC business school and the School of Entrepreneurship on the downtown UCD campus would further the mission of improving the business environment across campuses.