Clinical Research Working Group Report: Analysis of Existing Strengths, Critical Gaps, and Opportunities for Collaboration
May 2014

Analysis

Existing strengths

There is considerable clinical research being conducted at Rutgers upon which to build a major program in Precision Medicine clinical research. This includes a large number of IRB-approved clinical protocols (Table 1), peer-reviewed grant funding (Table 2) and high impact peer-reviewed publications (Table 4) that directly or indirectly relate to Precision Medicine. There are considerable clinical resources available through the large hospital centers in Newark and New Brunswick, as well as through over 16 integrated medical centers throughout the state. The potential for RBHS in providing leadership and oversight for the clinical and research infrastructure provides an unprecedented opportunity to integrate the clinical research processes across the large clinical network providing access to a large and diverse population of patients. This also provides an opportunity to partner with biotechnology and pharmaceutical companies to build basic and clinical research bridges that could allow Rutgers to take a lead in Precision Medicine research.

Table 1 Summary of Rutgers IRB approved clinical protocols*

Location	2014 Total Active Protocols as of 5/6/14
Newark	1,625
New Brunswick	1,769
Total	3,394

*Does not include central IRB services external to Rutgers

Table 2 Summary of Rutgers clinical research-related NIH funding

Agency	2009	2010	2011	2012	2013	Totals
CDC					$4,000,000	4,000,000
NCCAM	$903,553	$743,740	$0	$0	$0	$1,647,293
NCI	$2,457,940	$3,245,919	$3,851,408	$4,354,122	$6,422,957	$20,532,346
NEI	$271,889	$160,462	$0	$0	$0	$432,351
NHLBI	$1,995,556	$1,964,442	$2,355,616	$727,943	$691,201	$7,734,758
NIA	$2,522,346	$699,642	$871,830	$1,511,091	$277,034	$5,881,943
NIAAA	$891,617	$1,192,682	$856,333	$895,923	$964,963	$4,801,518
NIAID	$956,532	$732,230	$999,722	$834,868	$828,441	$4,351,793
NIBIB	$9,270	$0	$0	$333,266	$153,596	$496,132
NICHD	$1,901,279	$1,237,346	$447,339	$1,177,093	$1,047,606	$5,810,663
NIDA	$2,147,633	$4,188,632	$1,569,273	$1,832,265	$689,836	$10,427,639
NIDCD	$0	$0	$229,951	$200,123	$231,931	$662,005
NIDCR	$1,890,095	$1,152,262	$770,626	$861,076	$0	$4,674,059
NIDDK	$552,940	$534,306	$231,660	$467,127	$26,819	$1,812,852

NIEHS	$2,385,328	$1,767,425	$1,112,200	$1,279,647	$831,668	$7,376,268
NIGMS	$1,170,918	$425,909	$1,127,649	$1,346,022	$0	$4,070,498
NIMH	$2,709,454	$3,374,974	$2,927,976	$1,671,778	$1,914,356	$12,598,538
NINDS	$510,257	$3,936,534	$570,688	$3,909,482	$3,369,674	$12,296,635
NINR	$1,151,229	$1,250,606	$809,683	$33,139	$0	$3,244,657
Totals	**$24,427,836**	**$26,607,111**	**$18,731,954**	**$21,434,965**	**$21,650,082**	**$112,851,958**

Table 3 Summary of Rutgers clinical research-related publications

Category	Number of Publications Cited in PubMed
High Impact Clinical Journals*	73
Publications cited in PubMed from 2009 to 2013	7062

*High impact journal defined as impact factor >8

The collaboration with RUCDR, in particular, can be a key differentiator for Rutgers in the area of Precision Medicine research. RUCDR Infinite Biologics is playing a key role in research aimed at understanding the genetic causes of common, complex human diseases. RUCDR activities are enabling genomic discoveries leading to new diagnostics, predictive, preventive and therapeutic approaches for alleviating human suffering from a variety of diseases. RUCDR has resources to assist investigators with access to high quality biomaterials, technical consultation and logistical support. RUCDR as of April 2014 has nearly $120 million of funding and a broad portfolio of projects including collaborations with UCSF, Washington University, VA, and many others. As the world's largest university-based biorepository, RUCDR has been perfecting the science of biobanking, bioprocessing and analytics since 1999 and has established working relationships with several centers and institutes at Rutgers. For example, the Cancer Institute has an established program in Precision Medicine being recognized for playing a leading role in defining how to select patients for analysis, conduct bioassays in a clinically relevant time period and link genomic data to clinical decision making and new therapeutic approaches for patients with cancer. RUCDR Infinite Biologics is accredited by the College of American Pathologists, a worldwide leader in laboratory quality assurance and Rutgers is one of the first university labs in the world to earn this designation.

A major criteria for peer-reviewed funding in clinical research is impact and evidence of collaboration with other institutions and community outreach activity. This an area where there is considerable success at Rutgers, particularly as it relates to Precision Medicine. Table 4 represents selected inter-organizational collaborative research that is already established through Rutgers clinical investigators and specialty centers.

Table 4 Selected Inter-institutional clinical research collaborative efforts

Institution	RBHS Partner	Research Focus
Princeton University	Cancer Institute of NJ	Cancer research

Institution	RBHS Partner	Research Focus
University of Wisconsin	Cancer Institute of NJ	UM1 Clinical Research (NIH Grant)
Big 10 Cancer Consortium	Cancer Institute of NJ	Cancer research
Memorial Sloan-Kettering	Cancer Institute of NJ	Melanoma SPORE
RUCDR	Cancer Institute of NJ Department of Genetics	Genomics

Critical gaps

The ability to establish national prominence in clinical research requires access to appropriate patient populations, dedicated clinical investigators and institutional infrastructure to support the clinical research mission. The patient population is a major strength at Rutgers and there are a critical mass of clinical and translational investigators upon which to build a leading program. In general, the major critical gaps include the need to recruit additional faculty with a focus on Precision Medicine and a serious investment in integrated, university-wide infrastructure to support the clinical research goals. The following specific gaps were considered important to address:

1. **Critical Mass of Clinical Investigators:** A real effort in Precision Medicine will likely require additional recruitment of leading faculty, preferable with an established track record of funding, in Precision Medicine. As independent research centers, institutes and departments consider future recruitment, an emphasis on identifying candidates with a Precision Medicine interest in each of the disease areas would be helpful.
2. **Clinical Research Infrastructure:** A major obstacle for many potential clinical investigators is the lack of access to appropriate infrastructure for conducting, funding and supporting clinical research efforts, such as biostatistics, bioinformatics, pharmacy, research nursing and data coordination services. The committee recognized that resources are available for some groups and at some sites but this was not uniform and there was generally a lack of knowledge about what resources do exist and could be potentially accessed by current faculty and staff interested in pursuing clinical research. A “map” or website of currently available clinical research infrastructure and resources does not exist.
3. **Effective Communication:** The committee was concerned that communication across the institution was not effective in providing investigators with access to resources and a “silo” mentality could result in duplication of services and resources that would be more cost effective if provided at the RBHS or related level.
4. **Centralized Services:** The committee felt there was a significant need to centralize selected clinical research services, most notably budgeting, contracting, legal, and grant and contract management, including billing and collection processes.
5. **Dysfunctional Activation Process:** An important goal for achieving national prominence in clinical research is the ability to rapidly activate innovative clinical trials. The Working Group generally considered the Rutgers integration to have stalled this process and created an environment in which clinical protocol activation was too cumbersome and has made us much less competitive with other academic centers and could be a major obstacle to developing industry relationships.

6. **Lack of Standardization:** The committee considered consistency and standardization of processes and procedures across all campuses and felt it was critical to achieving national prominence in clinical research. At present, no standardization is occurring and is a significant obstacle to realizing the potential of the larger Rutgers resource. For example, there is no agreement between the Newark and New Brunswick IRB review process, which prevents us from competing for larger clinical trial opportunities and continues to foster an atmosphere of separation between the sites.
7. **Molecular Pathology**: This is a critical need for developing program in Precision Medicine and the recruitment of a national leader in molecular pathology will be critical to achieving national prominence.

Opportunities for collaboration

The Working Group identified numerous opportunities for growth and collaboration in clinical research. In general, the committee agreed that the large breadth and diverse nature of the patient populations available throughout the system could easily support national prominence in clinical research if the infrastructure and support services could be better integrated and streamlined. The potential to attract industry partners when we can deliver a rapid activation time, broad population and study sites and access to integrated informatics systems would help us achieve national recognition. Building upon one of the largest biorepositories in the United States by collaborating with Dr. Jay Tischfield represents a critical opportunity to focus on Precision Medicine, which is rapidly gaining momentum as a new paradigm for biomedical research in the nation. These interactions were also viewed as helpful for ultimately obtaining peer-reviewed funding by our faculty.

Another important opportunity was the access our faculty has to large clinical databases and registries that already exist within the institution. This is particularly applicable to programs in cancer, cardiovascular disease and infectious diseases. The health policy, public health and cancer population science programs provide additional opportunities to develop in-house expertise with data extraction and analysis of these databases. Further integration across campuses and networking with tissue repository and molecule genomics data would further strengthen the potential for preeminence in clinical research.

Other areas for potential collaboration include the availability of core services in some areas, such as biostatistics, research pharmacy and clinical research units. Although these resources are not available across all clinical research study sites, the existing expertise could be used, expanded and made available to others providing rapid improvements in clinical research resources for all faculty.

The Working Group also identified new funding opportunities, such as training grants and related mechanisms for supporting clinical research development, could be possible with a significant commitment to developing a focus on clinical research. Additional attention to faculty time and effort devoted to clinical research efforts would be helpful to allow the development of expertise in clinical research and a mechanism to incentivize faculty to conduct clinical research would be useful.