MGH
Translational and Clinical Research Centers

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Research Council and Clinical Research Council
September 6, 2016
MGH Clinical Research Center

- Formerly Bulfinch 4, Mallinckrodt GCRC
  - One of oldest “human laboratories” in US (1925)
  - Continuously funded by NIH since 1961

- Currently part of Harvard CATALYST Clinical Translational Science Program (2008)
  - Combines four major CRCs at Harvard: MGH, BWH, BIDMC, BCH
In addition to the CRCs, Harvard CATALYST provides additional centralized research support:

- Laboratory services
- Biostatistical consultation (with MGH CRP)
- Bioimaging
- Education (with MGH CRP)
- Pilot grants
- Training grants
- Assistance with multi-center, cross-institutional studies
MGH Clinical Research Center

Services Offered

- 4-6 bed inpatient unit- White 13
- Outpatient unit- White 13, CNY
- Off-site support- “scatter” studies (ED, ICUs, Health Centers)
- Help with design and conduct of clinical studies
  - Planning and design
  - Biostatistics
    o Power/sample size
    o Data collection and storage
    o Analyses
    o Reporting
  - Nursing orders and support
  - Clinical supervision, mentoring (NPs and MDs)
  - Nutrition orders and support
  - MRO program
Services Offered

- Nursing services (RNAs and NPs)
  - Monitoring: clinical and research
  - Administration of study medications and other interventions
  - Physiologic monitoring
  - Frequent sampling of biologic fluids
  - Clinical support (for non-MD Investigators)
MGH Clinical Research Center

Services Offered

- Metabolism & Nutrition services (RDs)
  - Specialized diets
  - Monitoring intake
  - Anthropometrics
  - Bone density, body composition measurements
  - Metabolic cart measurements- oxygen consumption
  - Exercise tolerance testing
Pediatric Studies

Specialized Support

• Children ≥ 1 mo
• 28 pediatric investigators with 12 Inpatient and 43 outpatient protocols
• Nursing
  – 7 RNs with specialty in pediatric practice
  – 3 Family NPs
  – 4 Adult NPs who can see children ≥ 13y
  – All RNs do pediatric phlebotomy and visits
• Nutrition
  – All RDs complete pediatric visits
  – One RD is pediatric certified
Active Protocols

Growth in Utilization (250 Approved)

![Bar chart showing the growth in active protocols from 2011 to 2015.](chart.png)
Outpatient Visits

Growth in Utilization

Annual outpatient visits

<table>
<thead>
<tr>
<th>Year</th>
<th>Visits</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012-13</td>
<td>4500</td>
</tr>
<tr>
<td>2013-14</td>
<td>4700</td>
</tr>
<tr>
<td>2014-15</td>
<td>5000</td>
</tr>
<tr>
<td>2015-16</td>
<td>6000</td>
</tr>
</tbody>
</table>
Departments Served

7/1/2015-6/30/16
N~ 6500 outpatient visits

- Medicine: 46%
- Pediatrics: 25%
- Psychiatry: 15%
- Neurology: 11%
- Anesthesia: 4%
- Dermatology
- Emergency Med.
- Phys.med/Rehab
- Radiology
- Surgery

Departments Served from 7/1/2015 to 6/30/16 with a total of approximately 6500 outpatient visits. The largest department is Medicine at 46%, followed by Pediatrics at 25%, Psychiatry at 15%, Neurology at 11%, and Anesthesia at 4%. Other departments include Dermatology, Emergency Med., Phys.med/Rehab, Radiology, and Surgery.
Of the 120 active Principal Investigators:

<table>
<thead>
<tr>
<th>Status</th>
<th>N</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Professors</td>
<td>24</td>
<td>(20)</td>
</tr>
<tr>
<td>Associate</td>
<td>32</td>
<td>(27)</td>
</tr>
<tr>
<td>Assistant</td>
<td>38</td>
<td>(32)</td>
</tr>
<tr>
<td>Instructors</td>
<td>26</td>
<td>(22)</td>
</tr>
</tbody>
</table>

Total number of investigators > 300
RN Intensity of Outpatient Visits

Investigator-initiated January-June, 2016

<table>
<thead>
<tr>
<th>Nursing Time (min)</th>
<th>N</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 None</td>
<td>17</td>
<td>0.68%</td>
</tr>
<tr>
<td>&lt;15</td>
<td>135</td>
<td>5.41%</td>
</tr>
<tr>
<td>16-30</td>
<td>200</td>
<td>8%</td>
</tr>
<tr>
<td>31-60</td>
<td>211</td>
<td>9%</td>
</tr>
<tr>
<td>61-120</td>
<td>720</td>
<td>29%</td>
</tr>
<tr>
<td>121-240</td>
<td>274</td>
<td>11%</td>
</tr>
<tr>
<td>&gt;240</td>
<td>135</td>
<td>5.41%</td>
</tr>
</tbody>
</table>

Total N ~ 2500
Support for Investigators

Industry-Initiated Studies

- Currently represent 15-20% of all CRC studies
- Study investigator/sponsor pays full costs
  - Outpatient/inpatient beds
  - Staffing- nursing, nutrition, other
  - Procedures
  - Lab tests
- Pricing of services available upon request
- Strongly suggest that investigators meet with CRC leadership before budgets submitted
RN Intensity of Outpatient Visits

Industry Studies
January-June, 2016

By Nursing Time
0 None
1 <15 min
2 16-30
3 31-60
4 61-120
5 121-240
6 241-420
7 > 420

N ~ 400
RD Intensity of Outpatient Visits

Investigator-Initiated and Industry

By RD Time
1 <15 min
2 16-30
3 31-60
4 61-90
5 91-150
6 151-240
7 > 240

N~2600
52% of all visits had a nutritional component
What’s New: Translational and Clinical Research Centers

- Combined unit with new MGH Translational Research Program.
- Translational Research Center
  - A new clinical research center dedicated to supporting first in human (Phase 1 and 2), bench to bedside types of study, and especially geared to working with industry
  - Unit being established with funding from hospital under direction of Mason Freeman, M.D.
Combined Clinical Research Center

- New combined unit on White 12, with part of White 13 retained (~50% larger than current CRC).
  - 18 inpatient beds
  - Outpatient space with procedure room
- The new combined unit will take advantage of CRC staffing and expertise and provide synergy between the two operations.
- Opening 10/18/16
What’s New: Funding and Charges

Currently: CRC Investigator-Initiated Studies

- Current funding $4 million per year from Catalyst CTSC plus hospital (DON) support
- All services for approved investigator-initiated protocols provided free of charge (beds, space staff) except for relatively rare services that are “above standard”, for example:
  - Nursing services that require 1 on 1 care
  - Frequent blood draws
  - DEXA scans- charge per scan
  - Weighed meals
- ~ 90 % of services free
Catalyst grant has ~ 1.5-years remaining.

The most recent RFA issued by NCATS has essentially defunded the CRCs.
- <1/2 funding (~$10 million per year) than we have in current CATALYST grant and
- CRCs are being defunded—specifically, no funding for space or staff to conduct studies.

MGH is formulating a plan to maintain as much support as possible.
Eulogy for the clinical research center

David G. Nathan¹ and David M. Nathan²

¹Dana Farber Cancer Institute, Harvard Medical School, Boston, Massachusetts, USA. ²Diabetes Center and Clinical Research Center, Massachusetts General Hospital (MGH), Harvard Medical School, Boston, Massachusetts, USA.
What’s New: Funding and Charges

Future: CRC Investigator-Initiated Studies

- MGH will find a way to support CRC.
  - Some CATALYST support allowed
  - Combined CRC and TRC will provide cost-efficiency
  - Added MGH support
  - However, even with added support, we project a $500,000 to $1 million gap/year
  - Investigators will need to kick in more
    o Grants
    o Cost “recovery”
What’s New: Funding and Charges

Future: CRC Investigator-Initiated Studies

• Investigators will continue to cover above standard services.
• The anticipated budget gap will have to be covered.
  - A CRC use fee will be charged to all studies.
  - Fee will be charged for ongoing and new studies effective May 1, 2018.
  - Fee will be proportional to visit frequency and intensity of work burden.
  - Anticipate fee to be $1,000-10,000 per study.
  - Can be charged to grants.
Charges for Investigators

CRC Industry-Initiated Studies

• Represent ~15-20% of all CRC studies
• Study investigator/sponsor pays full costs
  – Outpatient/inpatient beds
  – Staffing- nursing, nutrition, other
  – Procedures
  – Lab tests
• Pricing of services available upon request
• Strongly suggest that investigators meet with CRC leadership before budgets submitted
Charges for Investigators

**Translational Research Center**

- Most of the CRC industry-sponsored studies will move to TRC over time.
- Fee scales being established
- Study investigator/sponsor pays full costs
  - Outpatient/inpatient beds
  - Staffing - nursing, nutrition, other
  - Procedures
  - Lab tests
The TRC has two main components

• New clinical trial facility shared with CRC called the Translational and Clinical Res Ctrs (TCRC)

• New Administrative Infrastructure Support
  – Infrastructure provides expertise to MGH investigators interested in advancing discoveries into the clinic
    • Provides regulatory, manufacturing, clinical trial, etc expertise for drug and device development process
    • Can help PI’s with funding opportunities, but the TRC was not established to directly fund development projects
  – TRC infrastructure designed to work with local biotech and pharma companies to develop their therapeutics and to link MGH PI’s with these efforts
The MGH Translational Research Center

Pre-IND/Phase I Compounds/Devices
Academia/Biotech/Pharma

Phase IIb-III Ready Drugs/Devices

MGH Translational Research Center

Business Development

Project Feasibility

Project Management

Clinical Testing

Coordinated access to expertise

Phenotyping

Imaging

Genotyping

White 12 opening in October 2016
- 18 bed facility with state of the art tools for clinical trial work
- Combined CRC and new TRC staffing model to achieve better cost efficiencies
- Improvements in contracting and IRB timeframes worked out with Partners
- Regulatory, data management, and study design support for trials in TRC/CRC
- Business outreach to help MGH investigators identify external partners for collaboration
- Provide new venue for training in translational sciences for students and faculty
Vision for the TRC

• Improve overall clinical trial support for MGH investigators by creating new TCRC facility
• Provide opportunities for investigators to be involved in new therapeutics development
  – Advance internal projects and partner with external ones
  – Improve administrative processes with timelines compatible with time sensitive therapeutic work
• IRB Contracts Regulatory submissions Data Management
• Bring expertise inside that was previously only outside MGH
Vision for the TRC

• Leverage Boston-Cambridge biomedical ecosystem to make MGH a major partner in therapeutic development

• Create new research and training opportunities leading to new careers in the translational arena

• Generate new revenue streams that support research and the clinical research infrastructure of the hospital
MGH CRC -  http://massgeneral.org/crc

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