MACRO update, 2013-2015

This update report covers August 2013 – September 2015, and focuses on major developments since the 2011-2013 update.

1. Narrative summary of this year’s activity using non-statistical data

Overall, MACRO continues to do well, with **gradual organic expansion, strong investigator demand and enrollment performance, no ethical or regulatory issues, and a sound cost center model**, with stable client pricing since 2011. Major developments include further expansion into project management of multicenter clinical trials (including grant preparation), expansion of duties and academic structure of the Pitt student Research Associate (RA) program, joining of **Pulmonary, Allergy and Critical Care Medicine as our 4th parent Department/Division**, formal collaboration with the CRISMA Clinical Epidemiology Program, and new investigator clients from Neurology, Cardiology, Plastic Surgery, Pulmonary, Hematology, Hillman Cancer Center, General Internal Medicine, and others.

During this time period, we’ve continued to receive significant positive feedback from study sponsors, Pitt investigator clients, external Coordinating Center staff and investigators, and external investigators seeking to set up a similar research infrastructure:

“Thanks everyone. We could not have done it [the AST-109 study] without Denise for sure!!”
- Keith E. Gran, DPT, Associate Director, Clinical Operations, Astute Medical, Inc.

“Thanks so much for all your help with recruitment for the NAPS2-AS study. You have done a great job and it was real pleasure working with you.”
- Dhiraj Yadav, MD MPH, Associate Professor, Division of Gastroenterology, Hepatology & Nutrition, University of Pittsburgh

“...wanted to extend a big thanks to MACRO for the wonderful job you all have done. Enrollment is on a roll.”
- Sachin Yende, MD MSc, Associate Professor, Critical Care Medicine, U. Pittsburgh

“Just wanted to send a big note of thanks for the incredible job you are doing on SILVER. This has been a very busy month for Pittsburgh and we are definitely seeing the effect here at Yale.”
- Mary Geda RN, MSN, SILVER-AMI Project Director, Yale University

“Holy smokes! I think this is a new [enrollment] record! We are so fortunate to have the Pitt team as partners. Thank you for all of your efforts in making the study a success.”
- Sarwat Chaudry, MD, SILVER-AMI PI, Associate Professor of Medicine, Yale University

“Thanks so much for your wonderful hosting yesterday! We learned so much from you, and really appreciate you taking the time to share your experiences – Its a very impressive operation you have going, very inspirational for us in eastern PA.”
- Benjamin Abella, MD, MPhil, Associate Professor of Emergency Medicine, and Carrie Sims, MD, Associate Professor of Surgery, Penn Acute Research Collaboration (PARC), University of Pennsylvania

“Can you send me some of the stuff you presented on MACRO when you (ed - Clif Callaway) were here in Ann Arbor or any other information that might be helpful? Our CTSA director is really interested in discussing it and seeing how we could work to set it up here.”
- William Barsan, MD, Professor, Department of Emergency Medicine, University of Michigan
2. Specific accomplishments over the past year, including major activities and significant results

From February 1 2014 to February 12 2015, MACRO enrolled 166 patients in 18 interventional trials, and 243 in 8 observational studies for 29 PIs in 10 Departments/Divisions across 5 hospitals. Overall, these numbers represent a similar level of enrollment compared to 2011-2013, with a greater number of client Departments/Divisions and covered hospitals; **MACRO now serves many more Departments than our original founding three Departments.** We also continue to have no significant ethical or regulatory issues, and have held client costs relatively constant while operating at our goal of a net-neutral fiscal balance. **We also serve as the Coordinating Center for 5 multicenter trials of acute care** (4 federally funded). These trials have a combined budget of several million dollars, and cover prehospital trauma (PAMPER; STAAMP), biomarker guided antibiotic strategies (ProACT; co-coordinated with CRISMA Clin Epi), and infection prevention (CAPSIL, ANIDULA). We also perform key clinical research services to **support Pittsburgh’s involvement in two NIH-funded national research networks – NETT and PETAL.**

**Revenue has increased ~53% from FY11 to FY15 ($0.76M to $1.16M).** This revenue increase reflects growth in client demand (and thus MACRO staff “billable hours” for clients’ projects), and creation of additional service lines (data coordination, financial management).

Our FY15 budget is $1.15M (~4% higher than in 2010-2011), and we have $1.45M in fully executed cost center agreements for 34 studies for FY15 (These funds come from studies based in CCM (32%), Surgery (29%), Emergency Medicine (14%), and Medicine (ID, GI, Pulm, Gen Med, Renal, HVI, UPCI) (25%); %’s are based on dollar amounts, not number of studies.) 77% of our funding is federal. In previous fiscal years, planned budgets were higher than actual activity (with no impact on clients – as always, clients only pay for staff-hours used); **for FY15 revenues were 101% in comparison to the planned budget due to greater forecasting precision** allowed for by previous years’ cost model experience.

Through rigorous training and supervision, we have gradually expanded the duties of the Pitt students we hire as RAs; they now independently obtain consent for select studies. We have completed the **restructuring of our RA program to a Clinical Research Associate Internship program,** with greater academic structure and rigor. This process was inspired by conversations with the Pitt Office of Health Professions Advising and the School of Medicine’s Admissions Office. **More than half of our interns go to medical school.**

![What Happens Next?](image-url)

**What Happens Next?**

- Medical School: 56%
- Physician Assistant School: 15%
- Post-Bac: 7%
- Research: 10%
- Other: 12%
We also have begun to hire recent Pitt/RA graduates as “Super-RAs”, who function at a higher level than RAs, including supervisory work. These programmatic changes have resulted in greater cost-effectiveness and enrollment. We also held a June 2015 fundraiser to support presentations and meetings for our students, after a successful grant application to a local restaurant. Two pictures from the event are below.

We now formally collaborate with the CRISMA Clinical Epidemiology Program (Director – Dr. Sachin Yende), which has led multiple multicenter NIH funded studies. This collaboration resulted due to the similar work the 2 groups do; the natural synergy was obvious to the 2 Directors. Specific collaboration has included grant preparation for two multicenter clinical trials (PETAL – funded 2014; anti-PD1 – R34 funded 2015). The 2 programs are now coordinated by Ms. Barbara J. Early. Ms. Early received the 2015 Chancellor’s Award for Staff Excellence in Service to the University, the highest award the University of Pittsburgh grants to staff members in recognition of their outstanding contributions to the University. A picture from the May 2015 reception is below.

Also in May 2015, together with Dr. Christopher Ryan, the long-time Pitt IRB Chair, MACRO hosted our first “Nuances of Informed Consent in Acute Care Research” seminar for multiple current and future investigator clients. The seminar primarily consisted of role-playing sessions with “actors”, followed by feedback from experienced investigators and coordinators. Pictures from the seminar are below.
We continue our work with CTSI, and appreciate the increased support that CTSI has provided. We are one of 10 centers within the CTSI Clinical Research Resources and Facilities (CRRF) Core. Per preliminary data, from April 2011 to April 2015, the entire CRRF enrolled 15.6K patients. MACRO enrolled > 1 in 8 of all CTSI CRRF patients; specifically, 2016 patients (739 interventional, 1277 observational) into 48 studies (31 interventional, 17 observational).

3. Challenges and opportunities for 2015-2017

As always, our overall goal is to become the “FedEx” of clinical studies at UPMC – a valued service that everyone uses due to good service and price, has stable financials, and is a top organization to work for.

a. Managing growth / internal operations

We anticipate further diversity in client departments and investigators, based on increasing referrals and requests, from the McGowan Institute, Starzl Transplant Institute, Magee, Children’s Hospital, and others. As is our standard, we will carefully and organically grow, hiring appropriate staff, and vetting all growth opportunities within our multidisciplinary Executive Committee, and if needs be our Steering Committee.

Clinical research interns

As their scope of work has increased, it is vital we provide electronic tools to help our coordinators and students manage study tasks, and later screen and perhaps e-consent. We have had several discussions with a programmer at WPIC and anticipate a “beta” launch Winter 2016. The two coordinator supervisors of the Internship have also created a point system to track intern work quality and performance.

Coordinators

Overall work-to-staff ratio is fairly balanced. We will continue to monitor and manage the workload of the two top leaders, Barb Early and Mary Stefanick. We also plan to hire a data coordinator to assist the growing data needs of the trials for which we serve as coordinating center; we recently added a data coordination service line to our cost model. We will continue to liaise well with other coordinators; Sarah DiFiore (EM) has been of particular help with our regulatory needs. We also continue to prioritize individual 1-on-1 coaching by Barb, Mary, and David Huang of each coordinator, deploy coordinators towards their areas of strength, and encourage individual growth opportunities, including presentations at local and national meetings.
Accounting

We need to provide Dan Unikel additional accounting help. Long-term a 0.5 FTE accountant may be ideal; we will start by hiring an accounting student. This will assist in providing more timely billing for our services, and more timely completion of our annual cost center model. We also recently added a financial management line to our cost model, which Dan is responsible for. And, greater time for long-term financial planning will be of great use to help position MACRO for tight economic times.

Faculty

Workload for the physician Executive Committee members have been substantially decreased by reducing our study approval process to 2 physicians only, and by holding only 6 meetings a year. We also have starkly re-focused our approval process on protocol review and feasibility, including greater involvement of and communication with the investigator client. Continued coordination and communication amongst the physician leaders remains essential. The overall Director’s workload will have to be monitored, and possibly some of the work delegated to other physician Executive Committee members.

Investigators on Call

To facilitate enrollment, we have developed a call list of investigators who will be cross-trained in the basics of a number of trials (“go live” is Oct 1). When the PIs are unavailable, RAs or coordinators will have the option to contact these investigators to obtain time-sensitive consent or complete time-sensitive study tasks. For simplicity, we’ve started with ICU-based studies and ICU-investigator call, with an eye towards future potential integration with EM, Surgery, and Neuro studies.

b. Maximizing efficiency

Key will be creation of an electronic task management/screening tool that will enhance screening, enrollment, and quality improvement for multiple studies for multiple clients and Departments. We also continue to push for greater e-consent capability, and recently drafted an ICU study call schedule as above.

We also will continue to look for synergy and efficiency between MACRO and CRISMA Clinical Epidemiology. Both groups bring different cultures, strengths, and weaknesses to the table – we will optimize this collaboration via clear communication, transparency, and trust.

c. Expanding to other UPMC facilities

Our student operations at UPMC Mercy are supported only by the NETT studies and ProACT. We have flexibly adjusted our hours of coverage from 24 down to 12 hours per day to match enrollment. Greater interest from dedicated investigators at Mercy (and Shadyside, Magee, etc.) is needed to further expand coverage. While students at PUH can screen tracking boards at remote sites, it is difficult to respond to those sites.

d. Client service

Like FedEx, great service at a fair price is our goal. To achieve this, we’ve delegated more work to the interns, hired “Super-RAs” who command salaries between a RA and a coordinator, and continue to hire based on required skills and personality, not just degree(s). We also have made greater attempts at clarity in our contracts, with large bolded print to make clear the financial responsibilities and risk of the client PI.
Respectfully submitted,

David T Huang, MD, MPH on behalf of the MACRO Executive Committee

October 20, 2015