# From an Infrastructure to a Service-based Business Model: 5 Years of Mobile Clinical Research at the University of Michigan

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## Introduction

When the University of Michigan (UM) joined the ranks of the Clinical and Translational Science Award (CTSA)[1] consortium in 2007, the Michigan Institute for Clinical and Health Research (MICHR) was established to support the translation of medical advances throughout our institution. The importance of clinical research was recognized immediately and the clinical research unit (CRU), first established in 1977, was embraced as the newly named MICHR Clinical Research Unit (MCRU) to form the hub of our clinical translation infrastructure. Concomitant with this move, MCRU reevaluated its business model and realized that it no longer matched closely with the rapidly evolving research portfolio, which was increasingly driven by epigenetics, epigenomics, and other population-based research. In response, MCRU established a new mobile clinical research team, named MCRU 2U, as a way to transfer the research skills and expertise of our clinical research staff to the chair or bedside of our research participants. The guiding metric embraced as an indicator of the MCRU 2U "value-add" was the enablement of research that would be difficult or impossible to carry out in its absence. This paper outlines the steps taken in pursuit of this metric and the measure of its success, highlighting the impacts, benefits, and the lessons learned from 5 years of mobile clinical research at the University of Michigan.

## Implementing a Mobile Clinical Research Team

With the ubiquitous funding squeeze across academic research institutions, hybrid academic-business models are evolving[2,3] to meet the challenge of providing more and improved clinical research services with little or no increase in federal resources. Moreover, the growing population-based clinical research portfolio requires a larger and increasingly diverse participant population for successful completion, which means engaging more people from vulnerable groups for whom participation in clinical research represents additional barriers.[4] Although a relatively new concept, mobile clinical research teams are one exciting approach to address such issues and they are increasingly being employed to engage older populations who are confined to long-term care facilities,[5] to enroll and screen injection drug users,[6] to engage underserved ethnic populations,[7] and to service island communities.[8] Despite the rapidly growing interest in the concept of mobile clinical research this manuscript is, to our knowledge, the first published description of initiating, sustaining and growing such a service. Mobilizing our clinical research has transformed the overall business model of our CRU from an infrastructure-based to a service-based model, positively impacting our stakeholders from Principle Investigators (PIs) to participants, particularly for historically under-represented populations. Our findings may be useful to policymakers and university clinical research leadership who wish to adopt or expand the mobile clinical research model.

The main MCRU site is located in a specially designed, state-of-the-art (2009) facility on the central campus, close to the Medical School, the main hospital, and a host of UM medical institutes. A satellite clinic provides facilities for the significant participant population at the East Medical Campus (approximately 5 miles away), including outpatient examination rooms, nursing space, and specialized rooms and equipment shared with the Dental Research Unit. Our unit has five participant beds for overnight stays (approximately 120 per year) and another five that are just for ambulatory care (approximately 8,000 per year). The genesis of MCRU 2U was a single research study back in 2007, which required 200+ patients yet recruited only 20. Initially launched as an experimental approach to support this and other such "outlier" studies, MCRU 2U was activated just 145 times in the first year. This new "helicopter research" style service quickly became indispensable however, and by 2012 the annual participant total had risen to almost 2,500, bringing the number of new participants served during the 5-year CTSA funding period to more than 5,000. Today MCRU 2U represents 20% of our overall business and has vastly strengthened our ability to service our PI constituency by increasing participation by targeted groups; participants from our Mott Children's Hospital are up from four per year to 285, while participants in our Comprehensive Cancer Center have risen from eight to 861 each year. Despite such intense growth, the basic foundations of our model have remained remarkably simple. The principles underlying MCRU 2U are primarily to:

- Extend the practice of clinical research to areas outside MCRU, to be inclusive of not only inpatients and outpatients, but also their friends and their family members.
- Provide vulnerable participants with safe and convenient access to the clinical research studies being carried out across our extensive hospital complex.
- Redesign the participant experience to increase enrollment and reduce dropout.

The ultimate success of a mobile clinical research team depends on the effectiveness of the implementation strategy. *Figure 1* shows our Implementation Plan, which we have supplemented based on our experiences and the lessons we have learned. The first step involves building a strong strategic case, and this means providing hard evidence to directly link each identified need to the related service gap. Only by clearly demonstrating this link can the service gap form the basis of the impact analysis. In our case the research

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**Figure 1.** Implementation Plan for a mobile clinical research team, detailing strategy, implementation, operation and growth steps with Key Deliverables highlighted for each stage.

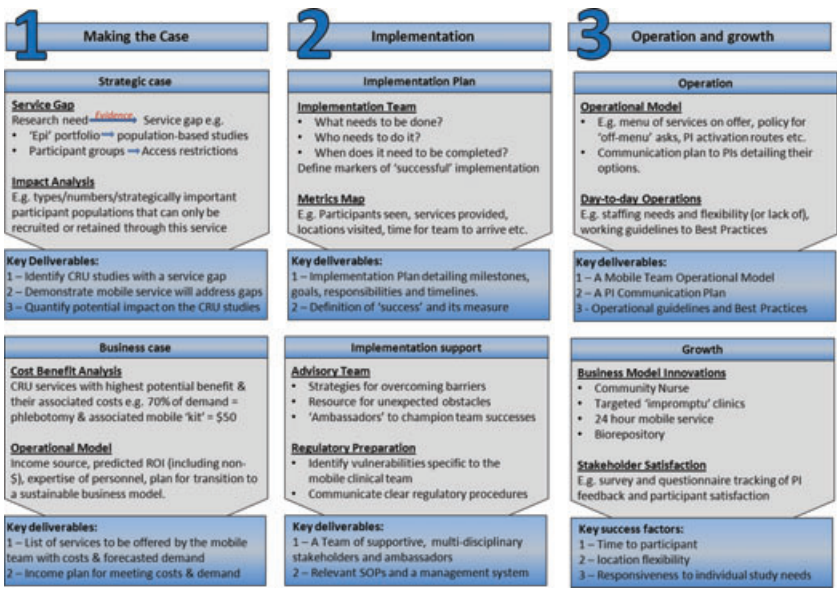
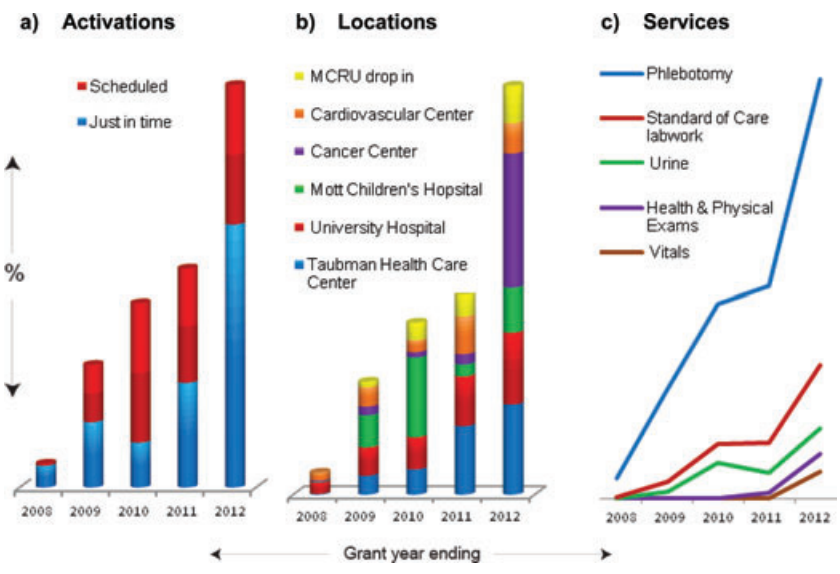



**Figure 2.** Growth of the mobile clinical research team during the first CTSA funding period; (a) MCRU 2U has serviced more than 5,000 research participants over the lifetime of the CTSA grant, with 2,414 participants in the grant year 2011–2012 alone (1,575 scheduled and 839 just-in-time visits). (b) The number of activations for each service area can vary widely depending on the protocol portfolio but overall the calls to each area are on the rise. The most popular locations for grant year 2011–2012 were the Comprehensive Cancer Center (861) and the Taubman Health Care Center (579). (c) The most requested service is phlebotomy, which for grant year 2011–2012 totaled 2,229.




needs were driven by an increasingly population-based research portfolio, high in epigenetics and epigenomics studies. Participant recruitment and retention was another tactical challenge[9,10] and when we examined our service gaps we discovered that limiting our participant base to our clinical research infrastructure was restricting access to services for strategically important participant groups. In particular, this was impacting our growing portfolio of hospitalized cancer patients and newly diagnosed Phase I participants, who require support at the bedside because they are unable to travel to the CRU. These issues added up to significant lost opportunities for us in our strategic case.

The mainstay of our business case involved generating a cost-benefit analysis to demonstrate that the proposal was justified. In our experience, more than 70% of the procedures for which MCRU 2U is called upon are simple phlebotomy (*Figure 2*). This is a very good indicator for assessing the return on investment (ROI) when introducing a mobile team; it can be largely a Medical Assistant (MA) driven service and the costs for phlebotomy supplies are modest (*Table 1*). Further, initiating and operating this service is highly cost effective because it involves no additional outlay for infrastructure costs. This cost calculation balances favorably against the potential opportunities in leveraging a huge new participant population, in addition to increasing the number and speed of study completions. In our case, our ROI has been profound and we have significantly increased our business overall (see *Figure 2*) without increasing costs. The design of our business model was driven by our strategic case and we determined that the value-add to our clinical research enterprise, albeit in non-dollar form, was potentially so significant that MCRU 2U should be fully funded through CTSA and institutional contributions. Therefore, in order to firmly establish this new service, the PIs were not charged for activating the MCRU 2U team, with the intention of transitioning to a sustainable business model at a later date. At this point we undertook no direct advertising campaign which was, with hindsight, the right decision. Requests increased through word of mouth about as fast as we could grow to meet them, so more demand could have swamped our nascent service model.

Implementation of this new service relied on the engagement of our most experienced staff. Clinical research nurses are highly specialized, operating at the front line of research efforts,[11] and this in-depth knowledge put them in a critical position to form our Implementation Team and drive our Implementation Plan, by clearly communicating the responsibilities and metrics of each individual and then holding them accountable for the outcomes. Their expertise was balanced by multidisciplinary input from other stakeholders via our Advisory Team, which included not only associated PIs and leadership, but also ethics and regulatory representatives. This collaborative helped us identify known barriers and develop effective strategies to address them, as well as develop clear goals, expectations, milestones, and timelines. High level champions form a crucial part of this process because they work with institutional leadership and the wider research

| Equipment needs for a hospital-based MCRU-2U member | Equipment needs for a community-based MCRU-2U member |
|---|---|
| Phlebotomy tubes, 2×2 sterile gauze, 23 and 21 gauge needles, central line supplies, syringes (3cc), alcohol and blue pads, tourniquet, coban, urine cups. | Phlebotomy tubes, 2×2 sterile gauze, 23 and 21 gauge needles, central line supplies, syringes (3cc), alcohol and blue pads, tourniquet, coban, urine cups. |
| Biohazard sharps container (small), gloves, band aids, towelettes (e.g., to clean area for urine collections), sample labels. | Biohazard sharps container (pint), gloves, band aids, towelettes (e.g., to clean area for urine collections), sample labels, blood pressure machine, and weight scale (kg). |
| Pager and/or mobile phone. | Pager and/or mobile phone. |
| Documentation,* e.g., IRB paperwork, protocol specific clinical sheet. | Documentation,* e.g., IRB paperwork, protocol specific clinical sheet. |
| Biohazard bags and ice pack for sample transport. | Biohazard bags for sample transport in specialized cooler. |
| Maps (for our vast hospital space), pens. | Mapquest, GPS system, portable clipboard storage case, pens. |
| Backpack (some members opt for a rolling suitcase when additional equipment is required). | Rolling backpack and wheeled crate. |

*Informed consent is not included here because this is verified online before the visit or a copy is provided during the site visit.

**Table 1.** The different equipment needs for mobile clinical research in the hospital and in the community. Because there are often additional or unexpected requests upon arrival, we routinely carry surplus supplied, e.g., extra tubes. Because the community-based nurse is provided with a car it is possible to include some heavier pieces of equipment.

community to address resistance and act as "ambassadors" to promote the team's successes. As we progressed, the Advisory Team helped us to identify new barriers and quickly make improvements or changes as needed. The development of a regulatory compliance and document management system is of distinct importance during this stage of the implementation, since a mobile team can be particularly vulnerable in areas such as participant privacy and sample integrity. A key issue here is that we monitored our progress from the start, by defining a Metrics Map to ensure that the data we tracked were actually related to our success (or not!) via a direct link to our Key Deliverables.[12] Some of these measured core outcomes have evolved over the CTSA funding period and the major metrics we now use to evaluate growth and success are shown in *Figure 2*a–c.

Although we did not actively advertise MCRU 2U, we did develop a Communication Plan by which MCRU PIs were made aware of the mobile services on offer and how they may access them. We offer four routes for MCRU 2U activation: (1) walk-in, where a PI may direct a participant to the CRU for immediate service; (2) Just-in-time, where a research team member is dispatched immediately to a hospital location external to the CRU; (3) prescheduled services at locations external to the CRU; and (4) the impromptu set-up of a temporary research "clinic" at any location. In terms of operation, the initial PI/study team request is assessed by MCRU staff and, depending on the complexity of the service requested, a Research Nurse or an MA is assigned. Importantly, when we introduced MCRU 2U we did not hire additional personnel, but instead reassigned and repurposed the original staff to incorporate this new service platform. We discovered that it is not feasible to identify a single individual to cover MCRU 2U requests because there are often multiple calls simultaneously for different locations. Even if several participants are in the same place, offering a single MCRU 2U team member could mean an unacceptable wait for the last one to be seen. Since CRUs typically operate under a feast-or-famine model, an area of initial concern here was that having a number of staff on MCRU 2U calls without any lead time could compromise the operation of the unit. In practice however, we have found that the speed and flexibility of the mobile team means we can work around them. In addition, we retain the right that, if required, the team member negotiates with the study team to redirect their participant to the unit, although in 5 years this has never been necessary. Over time we have developed working guidelines and best practices for the smooth operation of our service and, of the protocols we have developed, the most important are regulatory compliance, maintaining the chain of sample custody, and protecting the integrity of the sample (both physically and through documentation). Informed consent is protected in two ways with MCRU 2U; the first is for scheduled visits, where informed consent documentation is confirmed within the electronic medical records, and the second is for just-in-time appointments, where the documentation is provided to the MCRU 2U team member at the point of participant interaction, and is confirmed before any service is carried out. In the case of our community nurse, informed consent can be carried out in two ways; the first is before a scheduled visit, where the nurse can check the documentation in the electronic medical records or request a faxed copy. The second applies where the community nurse is participating in a population study, e.g., in a community center, where she partners with the study coordinator on-site and consent is obtained in real time. A particular strength of our model is that adaptations and improvements are made in real time through feedback during monthly meetings and it is fair to say that this is the foundation for much of our success in implementing and sustaining the team.

In the past 5 years we have consistently looked for innovative ways to service our clinical research studies better and we share here some of those which are, in our experience, the most valuable. Adding a community-based mobile research nurse, who travels up to 1 hour drive from our clinic, a distance of approximately 100 miles diameter, has built an additional layer of diversity into our participant base by avoiding exclusion on such criteria as social or economic grounds. However, because the resulting samples are obtained outside the regulated environment of the hospital they require new considerations, for example, regarding infection control and transport time. We have also found that pre-empting demand at strategic locations or time periods by setting up impromptu clinics is another highly efficient approach for population-based studies. As an MA-driven service, and because our CRU offers overnight services by a Research Nurse and an MA, we have extended our business model to offer a 24-hour MCRU 2U service at minimal cost. In addition, we are also looking at ways to network with primary care doctors who partner with researchers, as this is where patients will be seen repetitively.

Looking back over the past 5 years, we can clearly identify the three most crucial success factors for our mobile team. Almost

60% of participants recruited through MCRU 2U are new to research, many of whom had not planned to become a participant but agreed to participate in a study during a regular health service appointment. Their willingness to contribute largely rests on their participation not taking up a substantial amount of time and, as such, the leading key success factor for participants is speed. The average response for just-in-time MCRU 2U activations is just 19 minutes and this success is backed by survey measured impact, with 100% of MCRU 2U participants confirming that they would recommend participation to a friend.[13] From the PI perspective, responsiveness is the critical success factor, particularly for studies with a rare or limited target population where they must be able to take advantage of every opportunity to recruit a new participant. This means being willing to travel to wherever the participant is located and offering maximum flexibility on the services offered. MCRU 2U has six major centers within the UM health system where we regularly carry out services and for any other location, if we can physically get there, we will service a participant there. Similarly, if the need for a new service arises and it is physically possible to carry it out using equipment that can fit in a backpack, we will offer it.

## Conclusions and Future Prospects

MCRU 2U has positively impacted all our clinical research stakeholders and revolutionized the way our CRU does business. Researchers can now reach participants who would otherwise be inaccessible such as those in ICUs, and can more easily undertake complicated research studies such as those requiring the collection of time sensitive pharmacokinetics/biomarkers. The most important stakeholders however are the research participants and MCRU 2U participants are truly patients first, representing populations that have historically been excluded from participating in research due to mobility, impairment, socioeconomic and other factors. MCRU 2U has significantly reduced the barriers to participation for these groups.

The impact of the MCRU 2U service for this CTSA funding period is clear and, having had our award renewed in recent months, we are now looking forward to the next 5 years and even more progress. The breakneck pace at which technology is advancing means the population-based research portfolio will likely continue to grow rapidly, and mobile clinical research teams offer one of the most promising ways to meet the ever-increasing demand for sample numbers. Clinical research is a critical and dynamic component of the translational pathway and CRUs throughout the CTSA are working hard to preempt future challenges, as we ask ourselves: How we can position our clinical research services for the next generation of clinical research?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## References


**1.** Reis SE, Berglund L, Bernard GR, Califf RM, Fitzgerald GA, Johnson PC. National Clinical and Translational Science Awards Consortium. Reengineering the national clinical and translational research enterprise; the strategic plan of the National Clinical and Translational Science Awards Consortium. *Acad Med*. 2010; 85: 463–469.

**2.** Hutson S. Mayo tries new model in clinical trial business. *Nat Med*. 2010; 16: 949.

**3.** McCammon MG, Fogg TT, Jacobsen L, Roache J, Sampson R, Bower CL. From free to free market: cost recovery in federally funded clinical research. *Sci Transl Med*. 2012; 4: 141cm7.

**4.** Gemmill R, Williams AC, Cooke L, Grant M. Challenges and strategies for recruitment and retention of research participants: promoting the benefits of participation. *Appl Nurs Res*. 2012; 25: 101–107.

**5.** Greenspan SL, Nace D, Perera S, Ferchak M, Fiorito, G, Medich D, Zukowski K, Adams D, Lee C, Saul M, et al. Lessons learned from an osteoporosis clinical trial in frail long-term care residents. *Clin Trials*. 2012; 9: 247–256.

**6.** Lau C, Swann EM, Singh S. Behavioral and social science in HIV vaccine clinical research: workshop report. *Vaccine*. 2011; 29: 2509–2514.

**7.** Alcaraz KI, Weaver NL, Andreson EM, Christopher K, Kreuter MW. The neighborhood voice: evaluating a mobile research vehicle for recruiting African Americans to participate in cancer control studies. *Eval Health* Prof. 2011; 32: 336–348.

**8.** Forde M, Morrison K, Dewailly E, Badrie N, Robertson L. Strengthening integrated research and capacity development within the Caribbean region. *BMC Int Health Hum Rights*. 2011; 11(Suppl 2): S7.

**9.** Selker HP. Clinical research and the public: if not them, who? *Clin Transl Sci*. 2010; 3: 132–133.

**10.** Dwyer-White M, Doshi A, Hill M, Pienta KJ. Centralized research recruitment-evolving a local clinical research recruitment web application to better meet user needs. *Clin Transl Sci*. 2011; 4: 363–368.

**11.** Bevans M, Hastings C, Wehrlen L, Cusack G, Matlock AM, Miller-Davis C, Tondreau L, Walsh D, Wallen GR. Defining clinical research nursing practice: results of a role delineation study. *Clin Transl Sci*. 2011; 4: 421–427.

**12.** Pozen R, Kline H. Defining success for translational research organizations. *Sci Transl Med*. 2011; 94cm20.

**13.** Results of an internal survey carried out over 3 months (October to December 2011) and comprising 109 respondents.