**CMaT Projected Sustainability Scenarios – Low, Medium, and High**

CMaT Sustainability Plan

As part of the natural evolution of Engineering Research Centers that continue to operate beyond

NSF funding, CMaT pillars are preparing to meet the needs and constraints of external and internal funding opportunities. Some center programs will be more impactful if they are institutionalized and expanded. CMaT has also identified several external funding sources and strategies to continue to support research activities in the area of cell and gene therapy manufacturing. The self-sufficiency plan detailed below outlines CMaT’s value proposition, its eventual evolution into an Accelerator for Emerging Therapies (ACET), and the transition strategy.

##### CMaT’s Value Proposition and Vision for Year 10 of CMaT

ACET’s vision would be to establish a robust, sustainable, nationally-integrated, advanced biomanufacturing infrastructure to secure US leadership in advanced-therapy manufacturing and catapult the regional and US bioeconomy. ACET’s strategic plan is designed to build a strong, synergistic, and inclusive network of diverse, interwoven stakeholders – including local, regional, and national companies from across the biomanufacturing value chain, state and federal economic development partners, universities and two-year colleges, clinicians, patient advocates, regulatory and standards organizations, and community-development organizations. Beyond CMaT, ACET will fulfill several key voids in the emerging and advanced therapy development industry in the U.S. to rapidly accelerate time to market and industrialization, and create new, high-paying jobs – (a) enabling scalable, cost-optimized, and quality-by-design (QbD)-driven manufacturing; (b) providing specialized training across diverse stakeholders – from high school and two-year colleges to universities and current workforce; (c) establishing first-in-kind industry manufacturing technologies; (d) developing robust and resilient supply chain infrastructure; (e) and creating and maintaining a robust commercialization ecosystem for emerging biotherapies.

Seen as the future “umbrella organization” that will encompass CMaT and the Marcus Center for Therapeutic Cell Characterization and Manufacturing (MC3M, located at Georgia Tech), ACET will become a regional and national accelerator service provider for the advanced therapy manufacturing industry. The stakeholders include start-ups, small and medium-sized companies, and large companies in the biotherapeutics space (collectively termed “industry”). Importantly, ACET will have another key stakeholder base – clinical practitioners who are conducting early stage clinical trials for emerging therapies. Specific strategies for interacting with each of these stakeholders are outlined belong.

##### Future Funding Sources beyond Year 10 of CMaT

We will pursue and facilitate institutional adoption of some outreach, education and broadening participation programs so that they may continue to grow to their full potential and have a broader impact. We will also seek external funding opportunities for several CMaT pillars. It is anticipated that all existing partner institutions will continue to participate in sustaining research, education and workforce development, diversity and inclusion, and innovation ecosystem activities moving forward. Projects at partner institutions will be funded through subcontracts from large government grants, industry membership fees and industry sponsored projects. In addition to research, the center will continue to solicit support for student and curriculum development (such as the FMNet NSF grant, NIMBL NNMI funding for workforce development, etc.). These are ongoing key functions of CMaT and are important to industry partners. In Y5, the Georgia Research Alliance agreed to support CMaT to further develop our hands-on workforce training infrastructure and our commercialization infrastructure with a commitment of $1.5 million over three years. This infrastructure will also provide key support for Y10+ activities of ACET, such as our workforce training course offered with the International Society for Cell and Gene Therapy (ISCT). The CMaT self-sufficiency plan anticipates a diverse set of sources of funding following the end of NSF funding year 10 including:

* Institutional support from partner universities and the State of Georgia
* Philanthropic support
* Membership fees from industry partners
* Industry sponsored research projects
* Joint collaborative research projects with clinical partners
* Funded research from other NSF programs
* Funded research from other US government agencies
* Financial support from private foundations
* Fees for use of facilities
* Fees from professional development courses

Institutional/state support

CMaT major partner institutions have been strongly supportive of all our activities in research, education, diversity-inclusion, and innovation ecosystem. We have had strong line-item staff support from Georgia Tech. In addition to the administrative director, the institute has been supporting a full time compliance administrator, a full time finance administrator, supporting the ILO positions, and a full time industry support coordinator position. Similarly, other institutions have committed staff time to support CMaT. We expect that several of these positions will continue to be supported at the institutional level starting in Y10. Over the past 3 years, Georgia Tech Research Institute (GTRI) has contributed $1M in personnel and support for our automation efforts, and we have submitted a renewal application for these funds. The State of Georgia has provided significant capital funding for specialized equipment and facilities. The state issued $5M from State bond funding and the Georgia Research Alliance (GRA) provided $1.35M for equipment purchases. As mentioned above the GRA has also committed an additional $1.5 million to boost our commercialization activities and workforce training. At Univ Wisconsin, the Grainger Institute for Engineering provides administrative support for assembling large teams for grants and has initiated a focus on engineering and health care. These show the continuing commitment of the state of Georgia and partner universities, and we expect that such support will continue beyond Y10.

Philanthropic support

CMaT leadership has discussed with Georgia Tech Development and the Georgia Tech upper-level administration, and fund raising for the cell manufacturing effort in Georgia is a priority for Georgia Tech. In Y6, a plan was discussed with Georgia Tech’s VP of Development to increase the visibility of this effort to important donors, which has already resulted in 1) strategy sessions with Dr. Temenoff and President Cabrera and 2) face-to-face meetings of Dr. Temenoff and potential donors in Y7. Other opportunities for philanthropic support include endowed chairs for retention or recruitment of cell manufacturing faculty, and student or post-doctoral fellowships. The growing importance of cell-based therapies and the excellent progress being made by CMaT, the Marcus Center, and other partners will be emphasized in these discussions.

Industry membership fees and sponsored projects

So far CMaT has received $1.448 million in cash membership funds from industry partners and $2.154 million in in-kind support (i.e., $4.969 million of total support). Specifically, in Y6, $213,000 in cash support and $295,022 in in-kind support was received. In Y6, IPAB has grown to 43 members. This is expected to continue to be sustained over the remaining years of NSF support. Industry sponsored research has also started with two industry partnership projects underway and three more in negotiation. In addition, there are six ongoing industry projects in the CMaT-associated Marcus Center for Cell Characterization.

Federal and private foundation grant support

A significant source of support is expected to be new large grant funded research from NSF and other government agencies. There is a growing interest and emphasis on cell manufacturing among government agencies resulting in opportunities for large grant funding, as evidenced the 2022 Executive Order 14081, Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure Bioeconomy. Recent such opportunities include the NIH in-depth Cell Characterization Hub (IDCC) awarded to Geogia Tech (now in Y2. ~$1 million/year). CMaT investigators are entering Y2 of this award, with an anticipation that this would continue at least 5 years. In Y6, we have also pursued the NSF Engines ($170 million/10 years, selected as semi-finalists but did not advance to finalist status) and NSF Biofoundries awards ($24 million/6 years not awarded). We will continue to pursue these larger grant mechanisms in Y7+, as well as additional, smaller proposals from FDA, NSF and NIH, for further support of our cell manufacturing efforts.

Fees for use of facilities

The MC3M at Georgia Tech is an important source of support particularly with its specialized facilities for cell imaging and cell characterization. The ongoing CMaT relationship with MC3M is strong and includes support for CMaT projects. We have now created this as a cost center, with 2 companies renting space in the facility in the past year. Similar cost centers exist at the University of Georgia and the University of Wisconsin – Madison.

Fees from professional development courses

Professional development courses can be a significant source of revenue through webinars and short courses. This is particularly the case for the new technologies being developed in the cell manufacturing space. CMaT has partnered with the International Society for Cell & Gene Therapy (ISCT) to offer a virtual training course for industry. This course has been offered 5 times since 2022 with total attendance of 230 students to date. Due to its consistent popularity, a hands-on component of this course will be held at the Marcus Center at Georgia Tech in Summer 2024. We expect that in the next five years and then going beyond Y10 this will add significant recurring revenue.

**Sustainability Goals**

During Year 6, we have developed goals in each of 5 areas to help reach our overall objective of sustainability for key CMaT activities by Year 10. These will be further refined as we move through a full strategic planning process with each pillar planned for Summer 2024. Recent progress towards each of these goals is highlighted in italics after each goal.

1. **Academic Partnerships and Internal Stakeholders**

In order to maintain strong ties with each of our partners and continue to offer educational opportunities across the CMaT network, administrative support is important. We will work with administration at each partner to **institutionalize key support staff** (particularly those supporting our educational programs). *(Discussions underway in Y7.)*

1. **External Partnerships and Philanthropy**

**Improve visibility** for CMaT accomplishments to external stakeholders through improved website, newsletter and social media presence. *(Website updated and newsletter (re)started in Y7).*

While CMaT (and biomanufacturing broadly) was named in Y6 as an institutional priority for fundraising at Georgia Tech, CMaT-related research and **innovation should be emphasized for philanthropy/state/regional support at the other major partners**.For example,CMaT members at each institution should engage with their respective institution’s government relations groups to advocate at the state/regional level for the continued importance of funding for biomanufacturing. *(Discussions underway in Y7, including participation in a regional EDA Tech Hub grant in Puerto Rico.)*

1. **Innovation Ecosystem**

As we turn towards CMaT sustainability, we will further focus on providing “value add” for our industry partners. Specifically, we will continue to work to understand pain points for various aspects of our value chain and **encouraging engagement through sponsored projects**. We will also continue to work on encouraging start-ups and licensing of CMaT IP. *(1 new sponsored project under negotiation to date in Y7.)*

Since we see clinicians as one of the “end users” of our technology, it will be important to continue to **pursue strategic partnerships with clinical innovation partners**. *(Fred Hutchinson Cancer Center added as an Innovation Partner in Y7, joint publications with Emory University clinicians in Y6).*

We also plan to **add value to our innovation ecosystem colleagues by providing value to their own work**. This includes developing new and increasing existing education and training opportunities (discussed below), providing fabrication and facilities space for small companies in need, and performing some contract work as a Contract Development and Manufacturing Organization (CDMO). (*Developing full set of SOPs around CDMO work in Y7, 2 industry projects in Y6 that leverage the Marcus clean room facility space.)*

1. **Education and Diversity & Inclusion Programs**

In order to ensure that CMaT’s education and outreach programs will continue past Y10, we will look for both external (federal) as well as internal (institutional) support. We will write **federal grants to continue key educational programs,** such as a multi-site NSF REU.

We will **pursue philanthropy** to continue our post-doc and high school programs, as well as graduate fellowships where possible.

We will **increase enrollment in our training/re-training program** with International Society for Cell and Gene Therapy (ISCT) (*Course being expanded to include a hands-on component in Y7).*

We will **institutionalize educational offerings**, especially our popular cell manufacturing graduate courses, across our partner universities. (*New PhD program in Regenerative Bioscience was introduced at UGA in Y6*.)

1. **Research Portfolio**

In order to maintain ties between investigators across partner universities, the center will facilitate the submission of **at least one cross-institutional, multi-PI federal grant** per year for the next 4 years by CMaT faculty. Examples include the NSF Engines, NSF MSRI, future ARPA-H grants and NIH U- or P-awards. *(NSF Engines and NSF Biofoundries grants were pursued in Y6-Y7).*

**Projected Budget**

A budget for activities after Y10 and projected sources of income is found in Appendix XXI This year, as part of our planning efforts, we have developed budgets for low, medium, and high levels of support after Y10. The “low” level budget will allow us to maintain key educational and research activities, which are expanded in scope in the “medium” level projection. The “high” projection involves significantly more income from philanthropic and membership fees to further expand our research-related projects after Y10.

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**Projected Cost of Operation beyond Y10 of CMaT and the Potential Sources of Annual Income to Achieve Sustainability – LOW**



**Projected Cost of Operation beyond Y10 of CMaT and the Potential Sources of Annual Income to Achieve Sustainability – MEDIUM**



**Projected Cost of Operation beyond Y10 of CMaT and the Potential Sources of Annual Income to Achieve Sustainability - HIGH**

