



University of Colorado **Anschutz Medical Campus**

2024 Grubstake Application Webinar

October 4, 2024



The History of Grubstake



Charles C. Gates (1921 – 2005) with V-belts made by his family's company in the early 1900's, which revolutionized power transmission

Caltech

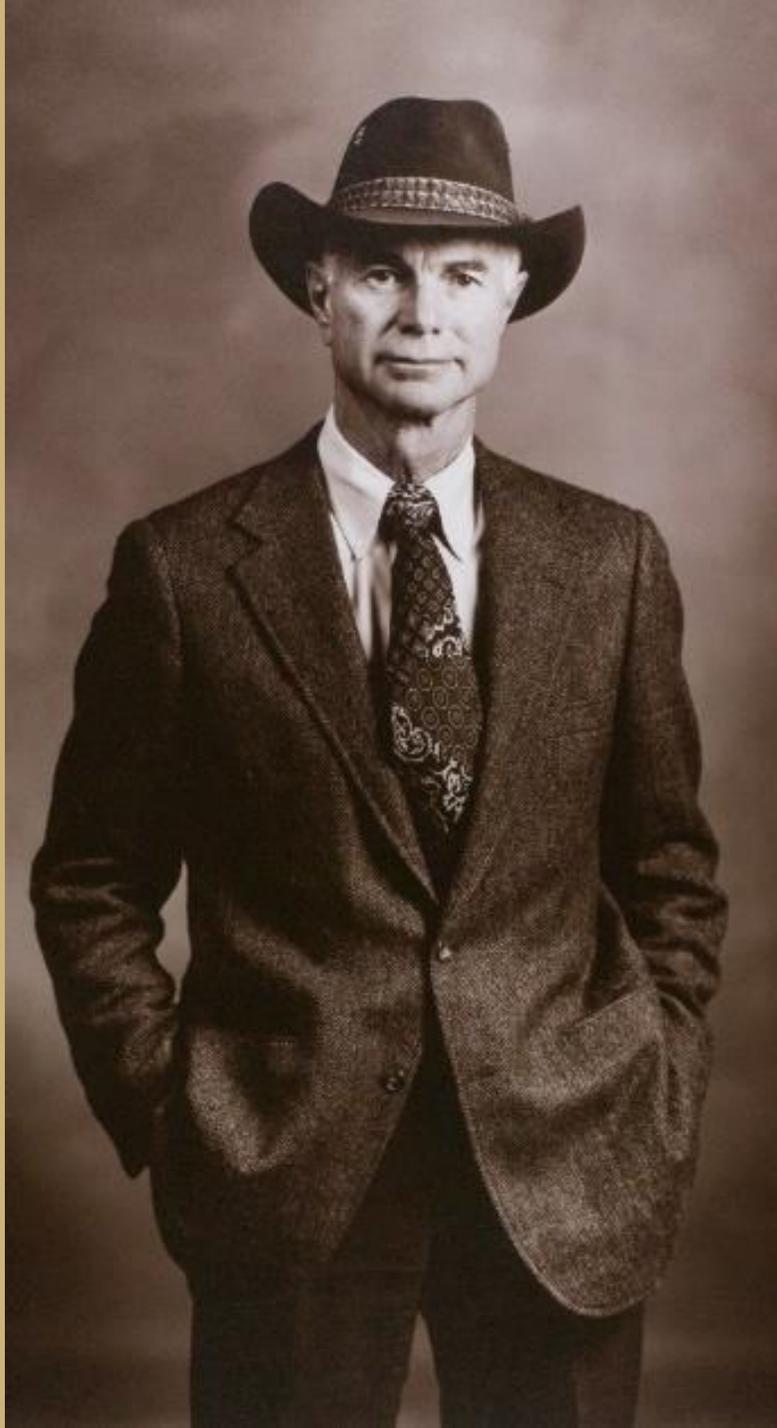
Gates Grubstake Fund

founded with a gift from former trustee Charles C. Gates in 1994



Grubstake: From grub (food) + stake (share). The term has origins in gold mining, where miners would get investors to fund their efforts in return for a cut of the profits. Earliest documented use: 1863.





“Science and knowledge aren’t magic, they take hard work fueled by deep curiosity, intellectual honesty, tenacity in the face of adversity, and hope for a better world.”

“Set the bar high; clear it; and raise it further.”

“No one does their best work alone.”

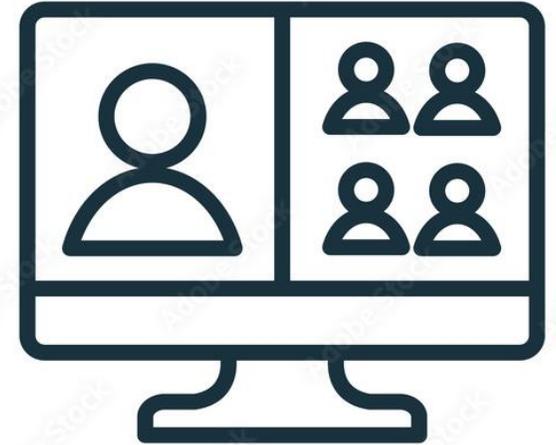
-Charles C. Gates

2024 Grubstake Webinar Topics To Be Covered

- Background and Purpose of the Grubstake Award
- Eligibility
- Application Process
- Review/Evaluation Process
- Specific Application Sections – Hints and Tips for Completion
- Review of Frequently Asked Questions (FAQs)
- Questions and Answers

**2024 GATES
GRUBSTAKE FUNDING
OPPORTUNITY** POWERED BY GATES INSTITUTE
AND CU INNOVATIONS

GATES GRUBSTAKE WEBINAR



WEBINAR

2024 Grubstake Webinar Objectives

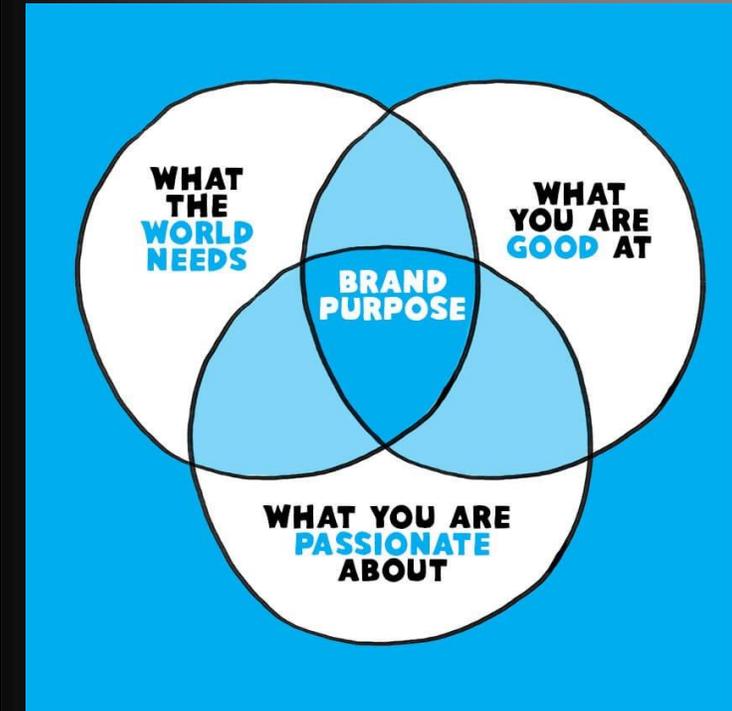
- Familiarize applicants with the process and timeline
- Clarify expectations for specific application sections
- Explain the evaluation process and criteria
- Describe awardee expectations and commitments
- Describe additional resources available

Ultimately, the Grubstake Committee wants all applicants to feel appropriately informed and supported throughout the application process and post-award grant.



Grubstake Background and Purpose

- Unmet Need:
 - Many research projects experience funding challenges.
 - Projects consistently run into ‘valleys of death’ throughout the product development lifecycle
- Our Solution:
 - Award supplemental funding to support high-impact, novel, early-stage (i.e., pre-clinical phase) projects
 - The fund aims to support projects with a focus on eventual patient impact in indications with high unmet medical needs





School of Medicine
UNIVERSITY OF COLORADO
ANSCHUTZ MEDICAL CAMPUS

uchealth

Who Qualifies?

- Academic researchers
- Non-profits
- Affiliation or direct collaboration with CU Anschutz (required)



Children's Hospital Colorado

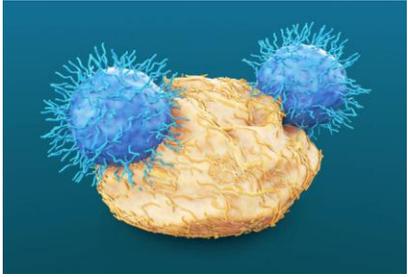


University of Colorado
Boulder



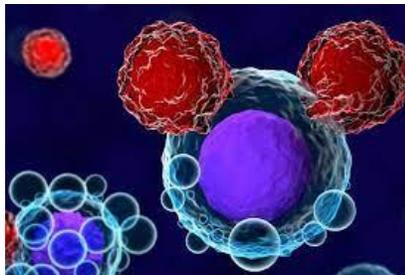
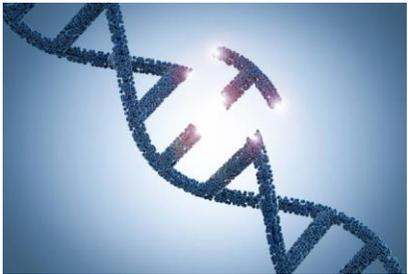
Gates Biomanufacturing Facility
UNIVERSITY OF COLORADO / ANSCHUTZ MEDICAL CAMPUS





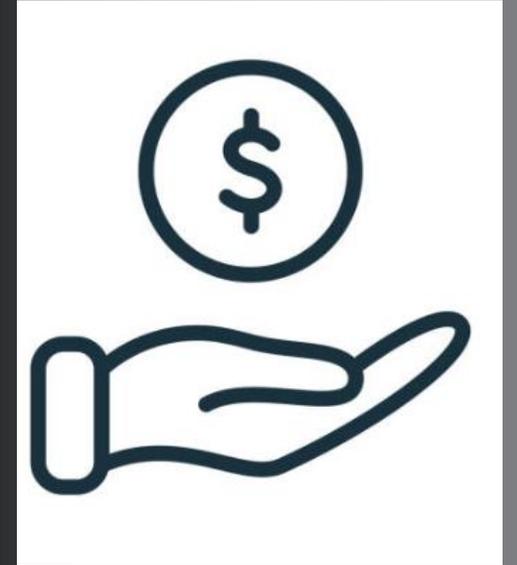
What Types of Projects Qualify?

- Cell and gene therapies (e.g., CARs, TCRs, immune effector cells, gene editing technologies, etc.)
- Biologics (e.g., recombinant proteins, RNAs, etc.)
- Small molecules that can reprogram cells in situ
- Stem-cell-based technologies
- Devices that induce cell reprogramming or tissue regeneration
- Companion diagnostics for any of the above products



Funding and Funding Distribution

- A **TOTAL** of \$1.5MM is available to support multiple projects
- Funding amount is commensurate with the product development stage and project objectives
- Project can be funded across multiple years (2 years max)
- Request the total amount desired
- Distribution will be in tranches
- Funding may be pulled for lack of progress



Previous Grubstake Award Winners

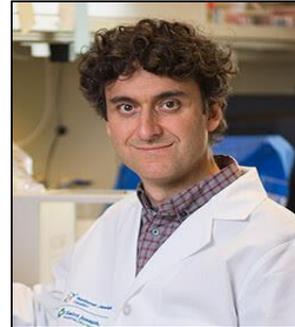
2023:

Mayumi Fujita, MD, PhD: "Modified CD4+ T-cells Expressing IL-37"

Jordan Jacobelli, PhD: "Engineered CAR T-Cells for Improved Solid Tumor Rejection"

Joshua Thurman, MD: "C3d Targeted CAR T-Cells for the Treatment of Solid Tumors"

Sujatha Venkataraman, PhD: "Next-Generation CAR T-Cell Therapy for Diffuse Intrinsic Pontine Glioma"



2022:

Ganna Bilousova, PhD and Igor Kogut, PhD: "Somatic Cell Rejuvenation for Skin Transplantation and Wound Healing"

Mi-Hyun Nam, PhD: "Restoration of Vision in Glaucoma through Cell Therapy"

Mark (Eric) Kohler, MD, PhD: "Adjunctive LAT-Activating Chimeric Antigen Receptor T-cells (ALA-CART)"

Daniel Sherbenou, MD, PhD: "Response Prediction for T-cell Engaging Bispecific Antibodies in Multiple Myeloma"

Evaluation Committee

The evaluation panel consists of:

- Approx. 8-10 core, voting members
- Gates Institute, CU Innovations, external members
- Expertise in start-ups, intellectual property, venture capital, financing, product development
- The committee may enlist *ad hoc* members with subject matter expertise as needed
- All members are either University-affiliated or under CDA



Evaluation Rubric

- The Evaluation Committee uses an evaluation rubric to score projects:
 - Designed to follow the general categories of the application
 - Mission Alignment
 - Scientific Merit / Intellectual Property
 - Patient Impact / Clinical Feasibility
 - Manufacturing and Regulatory Feasibility
 - Budget and Competitive Landscape
 - Uses weighted scoring (i.e., each scoring parameter carries a specific weight) in line with the application weighting



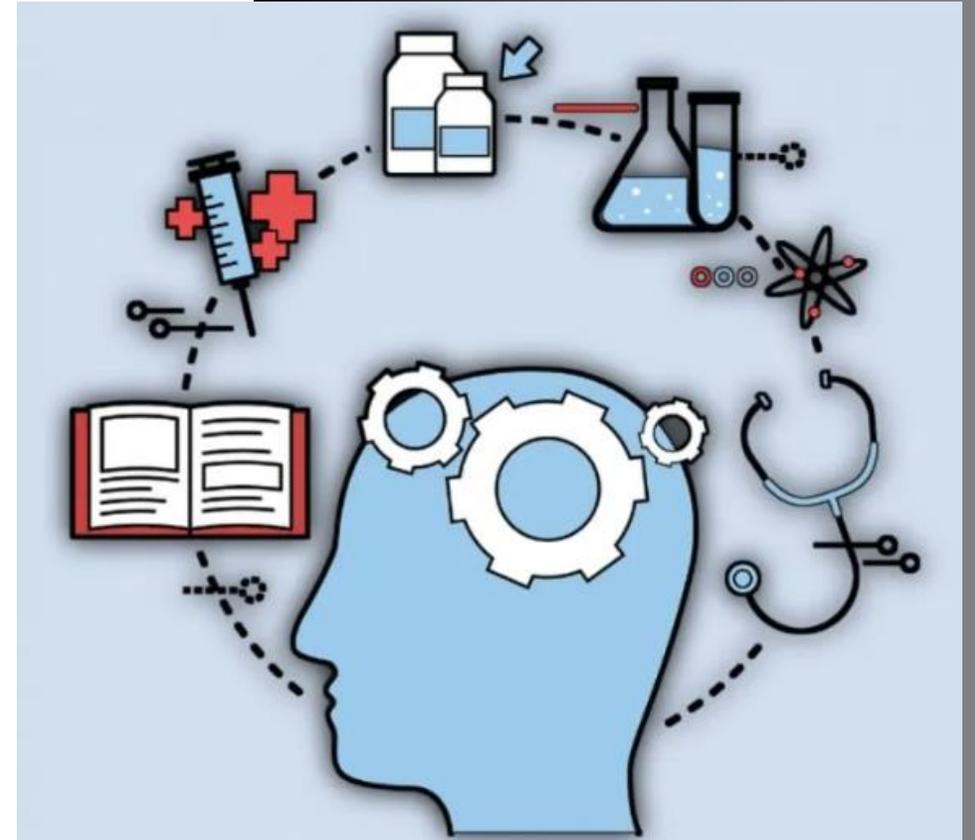
2024 Grubstake Application Important Dates

- November 15 – **APPLICATIONS DUE** through the portal
- Mid-January 2025 – Finalists notified for Pitch Night
- Late-January/early-February 2025 – Pitch Night practice sessions
- Mid/late-February 2025 – Finalist Pitch Night
- March 2025 – Awards Announcement



Important Application Notes

- **Specific Application Sections have weighted values:**
 - Scientific Merit (25%)
 - Mission Alignment (20%)
 - Patient Impact / Clinical Feasibility (25%)
 - Manufacturing and Regulatory Feasibility (15%)
 - Budget and Competitive Landscape (15%)



Important Application Notes

- The application must be submitted through the online portal
 - For those who want to work on the application offline, a word document is provided. Complete each section and cut/paste into the online application. [We advise all applicants to work offline first.](#)
- There are word limits for certain sections (varies by section)
- Each section holds a scoring weight and is evaluated accordingly
- Additional sections are provided for attachment of data, tables, figures, etc.
 - Supports multiple file types (png, jpg, tiff, ppt, doc, pdf, xml, xlsx)
 - Video can be used by embedding into a ppt and uploading to the portal
 - Number of attachments and file size limitations are provided (e.g., 1 figure, 25MB max per file, etc.)
 - [Take advantage of attachments to provide supportive and supplemental information](#)



Grubstake Application

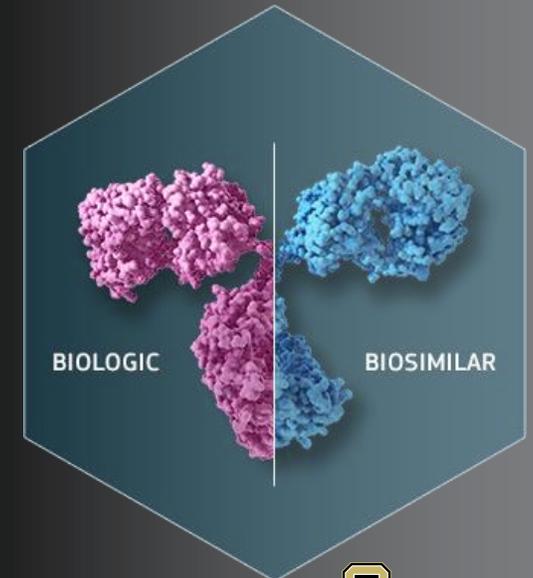
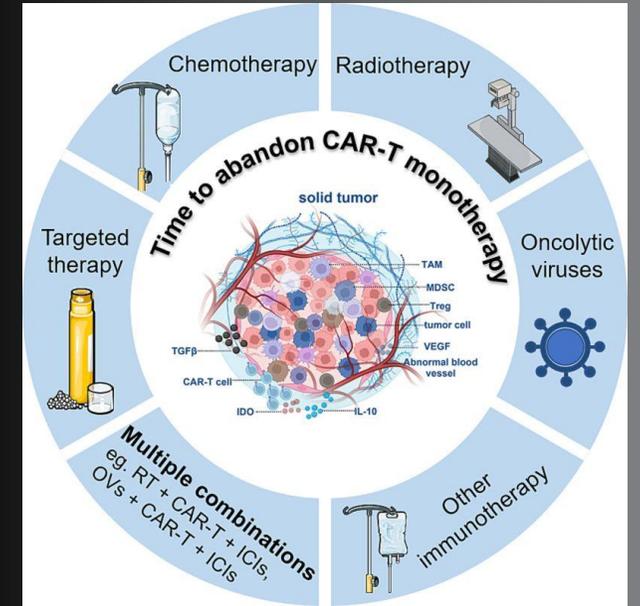
- **Part 1: Product Introduction**
 - High-level project background, product category, investigators involved, funding request, etc.
- **Part 2: Project Information**
 - Introduction
 - Product / Scientific Merit
 - Intellectual Property
 - Mission Alignment
 - Patient Impact
 - Manufacturing and Regulatory Feasibility
 - Budget and Competitive Landscape



Part 1: Introduction

General project overview and information including:

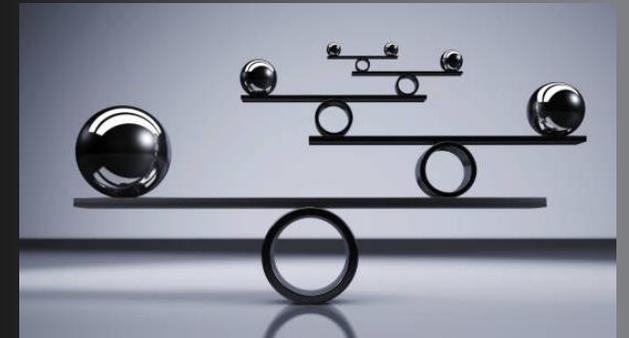
- Section is fairly self-explanatory
 - Principal Investigators
 - Overview of Project and Current Status
 - Funding Request and Budget Summary
 - How much is the request?
 - For how long? **Reminder: maximum duration of 2-years**
 - For what activities to advance the project?
 - To get to what proof of concept or value-add inflection point(s)?



Part 2: Project Information

Introduction:

- **600 word maximum**
- Be clear, concise, and compelling!!
- There is specific information required in this section
 - Summary of the technology, work conducted to date, and what still needs to be accomplished to demonstrate proof-of-concept
 - What is its purpose?
 - What unmet medical need is being addressed?
 - How does this technology either supplement, enhance, or replace the current standard of care?
- **Balance** the information between a **high-level summary** and **sufficient details** to convince a reasonably versed reviewer of the product differentiation.



Get the reader excited and wanting to know more!!

Part 2: Project Information

Product / Scientific Merit (25%):

- **1000 word maximum**
- Again, be clear, concise and compelling!!
- Specific requirements for this section include:
 - Product description
 - Development history
 - Future steps and milestones
 - These encompass near (1-2 year) and longer-term milestones
 - Include what development inflection points the Grubstake award will help accomplish
 - Risks
 - Include not only challenges this project faces, but also potential mitigation approaches
 - Challenges may include competing technologies, shifting patient standard of care practices, regulatory landscape, intellectual property, etc.
- Applicants are **strongly encouraged** to include graphs, figures and tables that support your scientific claims





Part 2: Project Information

Intellectual Property:

- Indicate if CU Innovations applied for intellectual property protection covering this technology and provide reference numbers
- If there is no related patent, provide information on the intellectual property strategy
- **It is required that all applicants submit an invention disclosure to CU Innovations prior to receiving Gates Grubstake funding**

Please contact CU Innovations for further assistance or guidance with Intellectual Property



Part 2: Project Information

We positively transform patient lives by advancing science through discovery, development, and delivery of biologic, cellular, and gene-based therapies.

Mission Alignment: (20%)

- **100-150 word** maximum per subsection
- Specific requirements for this section include:
 - Provide rationale and justification that your innovation aligns with and contributes to the **Gates Institute Mission and Values**
 - Include how your project aligns with the Gates Biomanufacturing Facility capabilities, wherever possible
 - Provide any campus, academic or industry collaborations and how each impacts your project

VALUES

- **Patient driven.** We prioritize patients, especially those with rare or difficult-to-treat conditions, through a commitment to develop, manufacture, and deliver innovative cell and gene therapies.
- **Find a way.** We overcome challenges with resilience and a solution-oriented mindset, turning setbacks into opportunities to advance science and change the practice of medicine.
- **“No one does their best work alone.” – Charles C. Gates.** Teamwork leads to excellence, where diverse skills and perspectives come together to achieve success.



Part 2: Project Information

Patient Impact / Clinical Feasibility (25%):

- **500 word maximum**
- Specific requirements for this section include:
 - Potential patient impact; How will this technology benefit individual patients?
 - Target patient population and high-level clinical trial design
 - Include a rough clinical synopsis for your product, if available.
 - Projected time to first-in-human clinical trial initiation
 - Is there a potential for this technology to treat rare diseases?



Part 2: Project Information

Manufacturing and Regulatory Feasibility: (15%)

- **500 word** maximum total for both sections
- Specific requirements for this section include:
 - **Details on Manufacturing Feasibility**
 - **Details on Regulatory Feasibility**



Part 2: Project Information

Regulatory Feasibility consists of the following:

- Describe your proposed regulatory strategy to first in human trials
 - What is the proposed regulatory pathway (i.e., CBER, CDER, CDRH; stand-alone product, combination product, diagnostic)? Seeking orphan drug designation? Phase 1 straight to pivotal?
 - Are there any current products/technologies that could be used as a guide?
 - Who do you intend to 'Sponsor' the investigational trials? Academic vs. Industry
- Milestones and estimated timeline to reach IND submission
 - Provide a high-level timeline to reach milestones (INTERACT, pre-IND, IND)
- Any potential regulatory issues/hurdles
 - Does your product or technology face any unique regulatory hurdles?
 - Is it first-in-class? New modality? Unique application? Gene-modified?
 - Provide proposals to mitigate any identified challenges

***Gates Institute Regulatory can provide further assistance
and guidance, as needed***

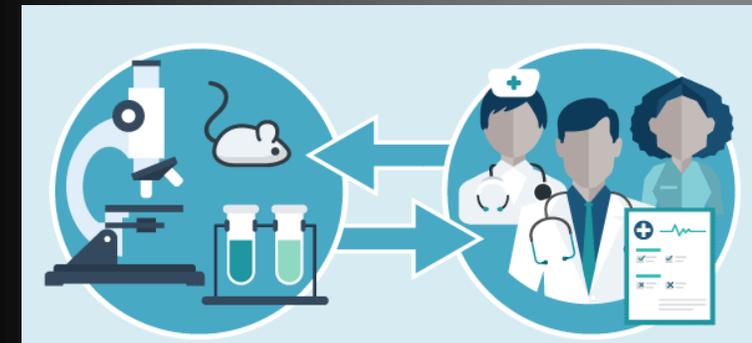


Part 2: Project Information

Budget and Competitive Landscape Plan: (15%)

- Consists of six (6) subsections:
 - Budget
 - Additional Support Required (200 word maximum)
 - Market Analysis (250 word maximum)
 - Competitive Landscape (250 word maximum)
 - Engagement (150 word maximum)
 - Bench to Bedside Experience (150 word maximum)
- **A PRELIMINARY BUDGET IS REQUIRED TO BE SUBMITTED WITH EACH APPLICATION**

Please reach out to Gates Institute Finance or CU Innovations for further assistance or guidance with Budget or Competitive Landscape, respectively



Part 2: Project Information

Budget and Competitive Landscape Plan: (15%)

- **Budget**

- Simple budget template is provided in the application
- Initial high-level budget should include major expected expenditures with approximate timing (e.g., equipment and material purchases, etc.)
- Amortize consistent, routine expenditures over the entire project duration
- Tie expense to a specific project aim or goal (e.g., to conduct animal model studies)
- If a multi-year project, provide a yearly budget (expenses in Year 1 vs. Year 2)
- **Budgets will be reviewed and vetted as part of the evaluation process**

- **Additional Support Required**

- Provide an estimated overall resource need (time, money, people) to advance your project beyond the Grubstake award goals into first in human clinical trials

Please reach out to Gates Institute Finance team for further assistance or guidance with Budget



Part 2: Project Information

Budget and Competitive Landscape Plan: (15%)

- **Market Analysis**

- We expect applicants to understand their target market, conduct market analysis research, and provide a summary of findings
- What is your target market? (e.g., patient population, indication, market value, etc.)
- What is the existing standard of care?
- What opportunities exist for growth or expansion into secondary/future markets?
- What are your assumptions regarding the future of the target market? (e.g., we expect the market to grow X%, CAGR, etc.)

- **Competitive Advantage**

- What competitors are there, and advantages does your product, technology, approach provide over similar products or the current standard of care or those in clinical trials?
- How will your product or technology continue to distinguish or differentiate itself?

Please reach out to CU Innovations for further assistance or guidance on Market Analysis or Competitive Advantage analyses



Part 2: Project Information

Budget and Competitive Landscape Plan: (15%)

“No one does their best work alone.” – Charles C. Gates

- **Engagement**

- Indicate how you, your team, and your project are connected to the greater Anschutz and/or Colorado community
- Explain the diversity and combination of expertise and experience your team brings with the proposed project
- How will the individual expertise/experience be leveraged to succeed?

- **Bench to Bedside Experience**

- Emphasize any prior experience with product/technology development from research to clinical trial, and how those experiences will translate to the current project



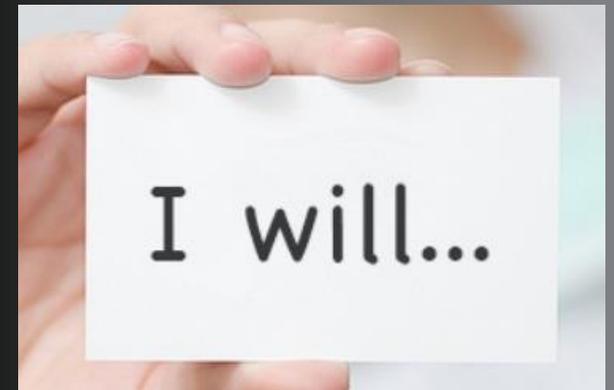
ENGAGEMENT



Follow-on Requirements/Requests

If you are a Grubstake Awardee, you are expected to...

- Provide regular scientific updates, **a minimum of every six (6) months**, to Gates Institute and CU Innovations
 - Publications or abstracts on campus or at scientific meetings
- Outcomes of using the Grubstake award
 - Publications, patent applications, etc.
 - Follow on funding, licensing opportunities
- Project progress or 'off-shoots'
 - New indications, new technologies
 - Next generation products
 - Discontinuations
- Recommend follow-on participation with Grubstake



Application Resources

- We encourage applicants to engage with the following groups if there are any questions during the application process:
 - General application: Gates Grubstake Planning Committee
Grubstake.award@olucdenver.onmicrosoft.com
 - Intellectual Property and Competitive Landscape: CU Innovations
 - Doreen Molk for Intellectual Property: Doreen.molk@cuanschutz.edu
 - Grant Peterson for Competitive landscape: Grant.Peterson@cuanschutz.edu
 - Budget:
Joleen.Bohnen@cuanschutz.edu
 - Manufacturing: Gates Biomanufacturing Facility
Matthew.Seefeldt@cuanschutz.edu
 - Regulatory: Gates Institute Regulatory group
Cheri.Adams@cuanschutz.edu



Q: Can for-profit, start-up organizations apply?

Answer: Yes. start-ups and for-profits may apply for Grubstake funding **IF** the organization is affiliated with CU Anschutz. **The award will go to the CU Anschutz investigator, NOT the industry entity.**

Q: Is my technology aligned with Grubstake/Gates Institute if it cannot be manufactured by GBF?

Answer: Yes. While it is preferred that your product or technology align with and could be manufactured using GBF, we acknowledge that there are limitations and may not always be the case. While this is preferred and considered during the evaluation process, it is not an absolute requirement or deal-breaker.



Q: Can I apply multiple times for a Grubstake Award?

Answer: Yes. A Principal Investigator may submit multiple applications for different projects within the same year or across multiple years. Our recommendation is to submit one (1) focused application within a Grubstake award cycle.

We also encourage those with projects that were not awarded in a previous year to re-submit a new application and include supplemental development information. The Grubstake Committee is willing to discuss what elements of a previous application may have had room for improvement.

Finally, we have eliminated the Second Tranche funding mechanism. If you wish to apply for additional funding to a prior Grubstake funded project, you must submit a new application for evaluation and consideration.



Q: How far should the budget timeline extend?

Answer: The budget provided within the application should be reflective of the major activities and milestones that you intend to have funded using the Grubstake award over the entire award period.

Keep in mind there is also an 'Additional Support' section under 'Budget and Competitive Landscape' for projected funding needs beyond the Grubstake award.

Q: Is a funding match needed?

Answer: No. The Grubstake award is intended to be a stand-alone funding mechanism for novel, groundbreaking, early-stage research projects. There is no requirement for an award match.



Q: How many applicants move on to Pitch Night?

Answer: It depends on the quality of the proposed projects and scoring competitiveness. Typically, we try to limit Pitch Night to 5-6 invited Finalist projects, of which the Evaluation Committee will then decide on which projects are selected for funding.

Q: If selected, who will be the audience at Pitch Night?

Answer: Pitch Night is currently scheduled to occur in mid- to late-February 2025. The audience will consist of Evaluation Committee members. In addition, ad hoc subject matter experts and representatives from CU Innovations and Gates Institute may be in attendance and participate as non-voting members.



Q: How many projects are selected for funding awards?

Answer: Again, it depends on the quality of the proposed projects and the requested funding amounts. Due to the variability now allowed in requested funding amounts, Gates Grubstake intends to fund multiple projects up to an aggregate amount of \$1.5MM.

Historically, when funding under the fixed amount model, Grubstake awarded 3-4 projects per year.



Q: How will Grubstake funds be distributed?

Answer: Gates Institute Finance will generate and issue a speedtype for each awardee. Funds will be distributed in tranches and in alignment with your vetted and agreed upon budget and milestone timeline. Therefore, it is important to be as clear as possible with your proposed budget within the application. We strongly encourage applicants to reach out to Gates Institute Finance with any additional questions.

Q: Are there any spending restrictions for Grubstake funds?

Answer: Yes. Please consult with Gates Institute Finance for additional information.



Open Q+A Session

