



National Organization of Research Development Professionals

One Grantmaking Organization's Approach to Impact Measurement

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Overview

About Gateway

Gateway's Clinical Trials Funding Program

- Who does Gateway fund?
- What kind of research does Gateway fund?
- What is involved in the grant application process?

Gateway's Impact Framework

- What is it?
- How was it developed?
- How does it work? How is data collected on the impact of the funding?
- What has been the impact of the funding?

Lessons Learned & Feedback from the Field

Closing Remarks + Q&A



About Gateway

Vision

To shape a world in which a cancer diagnosis is no longer feared

Mission

To fund meaningful and breakthrough clinical trials worldwide that help people living with cancer to feel better, live longer and conquer cancer TODAY!

Reach

- A 501(c)(3) public charity that funds treatment-based Phase I and Phase II cancer clinical trials, exploring better,
 - less toxic treatments and cures for all types of cancer
- 99 cents of every dollar received directly funds cancer clinical trials, thanks to generous underwriting by Cancer Treatment Centers of America (CTCA)
- Gateway has funded more than 150 clinical trials worldwide, since its inception in 1991

Differentiators

- Patient-centered approach – incentivize researchers to adopt patient-centered outcomes; carefully measure degree to which they, and we, have placed patients at center of our work; patient representatives sit at every level of organization, up to and including Board of Directors
 - Transformational science via effective clinical trials
 - Targeted therapies to tailor treatment to unique biology of each patient
- Interactive medicine has been a hallmark of our research focus*



Gateway's Clinical Trials Funding Program

We are focused on funding early stage (Phase I and Phase II), patient-centered clinical trials across all types of cancers.

A Unique Funding Model

Funding is awarded to researchers each time a patient is enrolled *and* treated in a Gateway-funded study.

A Balanced Portfolio

We strive to fund clinical trials in the following basic research areas for all cancer types:

- Integrative Medicine (CAM, Quality of Life)
- Novel use/combination of existing drugs
- New therapy/drug discoveries



Who does Gateway fund?

Does Fund

Investigators from any academic, nonprofit institution and medical center who:

- Are ready to conduct a clinical trial in cancer research – one which will have an immediate impact on cancer patients
- Have a proven track record as a clinician, researcher, or primary investigator

Does **Not** Fund

- CTCA physicians
- Biotechnology companies
- Pharmaceutical technology companies



What kind of research does Gateway fund?

Does Fund

- **Investigator (PI)-initiated** clinical trials
- **Patient-Centric** – research that benefits patients, not only science
- **Innovative with a sense of urgency** – research that is novel, advances the field beyond more conventional, toxic therapies
- **Intelligent selection of therapy** when feasible, with a **high potential for success**, for example:
 - **Personalized medicine**
 - **New and emerging treatment modalities** (e.g., immunotherapy, targeted drugs, which may be combined with complementary therapies)
 - **Translational research with human biospecimens** IF it directly leads to or supports the clinical trial in the grant and/or it is used to interrogate the tissues of patients within a trial to understand actual patient response or toxicities experienced to inform future work

Does **NOT** Fund

- Industry-initiated clinical trials
- Studies that focus only on pharmacokinetics with no clinical activity
- Basic research and pre-clinical research in animals
- Early prevention, detection, retrospective, educational studies, or Comparative Effectiveness (CER) studies
- Placebo only agent arms



What is involved in the grant application process?

Application

Access Gateway's online Grants Management System (GMS):
<https://gatewaycr.fluidreview.com/>

Review Gateway's [Funding Guidelines](#) to self-check against funding criteria

Submit a Letter of Intent (LOI)

Consider Gateway's Timeframe:

- LOIs accepted on an ongoing basis
- Full grant applications are accepted by invitation only, reviewed quarterly

Consider Gateway's Funding Range & Grant Term:

- Total funding range \$200K-\$800K
- 2-year or 3-year grant term
- 1-year grants limited to venture fund collaborations

Review

2 Review Rounds: (1) Letter of Intent; (2) Full-grant application by invitation only

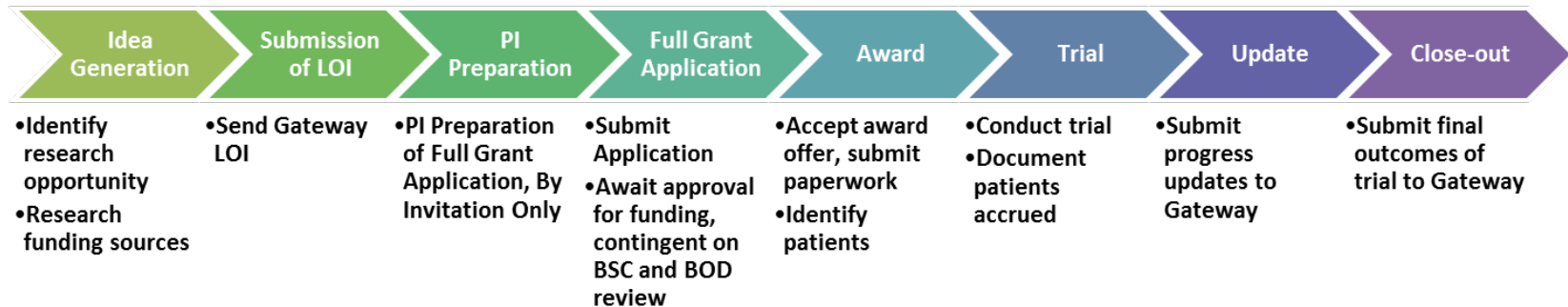
2 Review Committees: (1) Evaluation of science, patient impact, budget and conformity to Gateway's mission by Board of Scientific Counselors (BSC), including Patient Advocates; (2) Approval of funds by Board of Directors (BOD)

4 BSC > 4 BOD Meetings: Quarterly and sequentially pre-scheduled meetings of the BSC (typically, 2 in-person, 2 teleconference) and BOD (all in-person)

Funding Criteria: Significance & Patient Impact (25%), Feasibility (25%), Innovation & Originality (20%), Conformity to Gateway's Mission (15%), Reasonable Budget (15%)



Gateway Grant Management Process – *Researcher's Point of View*





Gateway's Impact Framework: *What is it?*

A Measurement Approach

- An approach to measuring the impact of Gateway's investments in cancer research.
- A measurement model that includes the outcomes, indicators, data sources and collection methods used to support Gateway's impact.
- It is about measuring the outcome, *not* the activities of Gateway's investment in cancer clinical trials.

A Strategic Approach

- ... by which the needs of patients and caregivers are understood and reflected within Gateway's funding program and brand messaging.
- Summed up with an impact statement – the articulation of the strategy, which everything ties to and from which the framework's outcomes are derived.
- The impact statement drives the framework's outcomes and indicators.



Gateway's Impact Statement

Gateway invests in the next generation of potential breakthroughs in patient-centric cancer research in order to drive **transformational advances in cancer research TODAY.**

In the near term, we will do this by supporting clinical trials that effectively tailor cancer treatment to the unique biology, environment, and needs of each patient.



Outcomes Supporting Gateway's Impact

| Gateway Impact Framework ©2014 Gateway for Cancer Research | | | |
|---|---|------------------------------------|---|
| Key Strategies | Patients Have a Voice | Patients Feel Better & Live Longer | Patients Contribute to Overcoming Cancer in the Future |
| | Amplify patient voice in Gateway's decision-making | Improve quality of life | Create a shared sense of urgency |
| Outcomes | Increase centrality of patient voice for Gateway supported trials | Improve health outcomes | Improve the standard of care via transformative discoveries |
| | | | |



Gateway's Impact Framework: *How was it developed? (People)*

Launched strategic planning process

Hired **impact consultants**

Interviewed a cross-section of
stakeholders + experts

- Patient Advocates
- Scientific Advisors
- Clinical Researchers
- Organizational Leadership
- Key Staff Members
- Peer Organizations
- Donors





Gateway's Impact Framework: *How was it developed?* (Process)

Began with questions

- What is the current state and capacity of outcomes tracking?
- What are its current strengths and weaknesses?
- What do we need most from our impact framework?

Defined basic elements of an impact framework

- **Activities** – the actual work of the research. From inquiry to basic, translational, clinical phases.
- **Outcomes** – the near term changes we see as a result of research. For example, patients feel better, burden of treatment is reduced (situational). Changes to doctor patient communication practices or new clarity around decision trees in navigating treatment (behavioral). Improving chances of 5-year survival (status).
- **Impact** – the cumulative effect of these outcomes can be correlated with a longer-term impact. Breakthroughs in the field, moving the needle on survival rates, conquering cancer.

Compared Foundation Approaches

- **Traditional Foundation** – “*Did the research do what it said it would do?*”
- **Progressive Foundation** – “*What is the **meaning** of the research results?*”

Reviewed Instruments

- Fact-G Questionnaire (www.Facit.org)
- Herth Hope Index (Contact author directly for permission to use: kaye.herth@mnsu.edu).



A Comparison of Foundations

| Foundation | Impact Concept | Measurement Approach |
|-----------------------------|-----------------------|---|
| Cures Within Reach | Repurposing Compounds | <ul style="list-style-type: none"> • How repurposing increases patient access to treatments • At field level, how elevated the concept of repurposing is • At operational level, how much awareness and fundraising results |
| CureSearch | Acceleration | <ul style="list-style-type: none"> • How much organization is able to speed up research pace • At field level, how organization is able to remove barriers to acceleration • At operational level, how much awareness and fundraising results |
| Conquer Cancer | Scholarship | <ul style="list-style-type: none"> • Publishing record, career advancement, leveraged funding, leadership positions achieved by investigators |
| Stand Up To Cancer | Collaboration | <ul style="list-style-type: none"> • Dream teams |
| Gateway for Cancer Research | Innovation | <ul style="list-style-type: none"> • About the outcomes, <i>not</i> the activities. • Outcomes and indicators grounded in patients having a voice, patients feeling better and living longer, and patients overcoming cancer in the future <ul style="list-style-type: none"> ○ What do the research results suggest for future patients? ○ How does this research advance the field's standards of excellence? ○ How has it changed our thinking? ○ Where did it break new ground, improve standards of care, or uncover a novel approach? ○ How did it feed the field with new and talented investigators? |



Gateway's Impact Framework: *How was it developed? (Implementation)*

Acquired approval for adoption and implementation from Gateway's Board of Directors

Increased staff capacity to oversee more rigorous application and enhanced reporting process

Overhauled systems and processes to support tracking, collection, and analysis of more extensive data

Conducted a retrospective data analysis and input data into grants management system

Spent last 12+ months collecting data in support of the framework to report an aggregated impact of Gateway's grants investments to donors and stakeholders





Gateway's Impact Framework: *How does it work?* *How is data collected on the impact of the funding?*

Select Indicators Support Each Outcome

Indicators within each Outcome are **defined within a proprietary roadmap**

Data is collected Inside & Outside Gateway's online Grants Management System (**GMS**)

Reports from GMS paired with analytic **report generator** used to populate **snapshot** of Impact Dashboard

Impact Dashboard is a **work-in-progress**, reported to Gateway Board of Directors, quarterly

Data Sources Inside GMS

- Full Application
- Semi-Annual Report
- Final Report
- Annual Follow-Up Report

Data Sources Outside GMS

- Administrative Records
- [Get Involved Section of Gateway Website](#) supported by **Patient Voice Quick Card**



Gateway's Patient Voice Quick Card

#HEROESAMONGUS

THANK YOU!

**CLINICAL TRIAL PARTICIPANTS
MAKE A DIFFERENCE IN THE
LIVES OF CANCER PATIENTS –
NOW AND IN THE FUTURE**

Gateway invites you
to voice your thoughts
on research priorities
and share your cancer
story.

**GATEWAY
FOR
CANCER
RESEARCH**
gatewaycr.org

WE VALUE YOUR IDEAS AND SUGGESTIONS

Gateway invites patients, caregivers and patient representatives to submit research questions for consideration to help improve the health and well-being of patients who are, will, or have completed cancer treatment. Gateway will review and evaluate all questions to prioritize research topics for funding.

Please submit a research question on our website, here:

gatewaycr.org/patient-questions

SHARE YOUR STORY

We invite patients, caregivers and patient representatives to share their cancer stories and their journeys. Help us give hope to people around the world by sharing your story. It's stories like yours that provide comfort and courage to others whose lives have been touched by cancer. Gateway may use your story to raise awareness and encourage more funding for clinical trials.

Share your story on our website, here:

gatewaycr.org/share-your-story

GATEWAY FOR CANCER RESEARCH

Gateway for Cancer Research is a nonprofit organization committed to funding innovative cancer research that helps people with cancer to feel better, live longer and conquer cancer TODAY!

**99¢ OF
EVERY
DOLLAR**

99 cents of every dollar Gateway receives directly funds Phase I and Phase II cancer clinical trials at leading research institutions across the country and abroad.

Learn more about Gateway
by visiting gatewaycr.org.





Gateway Impact Framework ©2014 Gateway for Cancer Research

| Pillar 1: Patients Have a Voice | | Pillar 2: Patients Feel Better & Live Longer | | Pillar 3: Patients Contribute to Overcoming Cancer in the Future | |
|---|---|--|---|--|---|
| Outcomes | Indicators | Outcomes | Indicators | Outcome | Indicators |
| Amplify patient voice in Gateway's decision-making | # of patient voices engaged in shaping Gateway's priorities | Improve quality of life | % of patients seeing a reduction in interference with life between design stage and trial stage | Create a shared sense of urgency | # of unique funding collaborations and partnerships |
| | # of caregiver and family voices engaged in shaping Gateway's priorities | | % of patients gaining hope for the future | | % of Gateway supported trials that progress to next phase of research |
| | # of stakeholder questions addressed in Gateway-funded research | | % of patients maintaining or improving life quality | | # of Gateway supported trials that reach clinical practice |
| Increase centrality of patient voice for Gateway supported trials | # patient representatives involved in Gateway's decision-making | Improve health outcomes | # of patients accrued | Improve the standard of care via transformative discoveries | # trials that would not have proceeded without Gateway support |
| | % of funded trials that include robust patient-centered outcomes | | % of patients whose cancer responds partially to treatment | | \$ additional dollars leveraged by Gateway investments |
| | % of funded trials that incorporate consultation with patient representatives | | % of patients who experience complete response or remission | | # new NCCN treatment guidelines that relate to Gateway supported research |
| | | | Optional: Progression-free OR Overall survival rate | | |

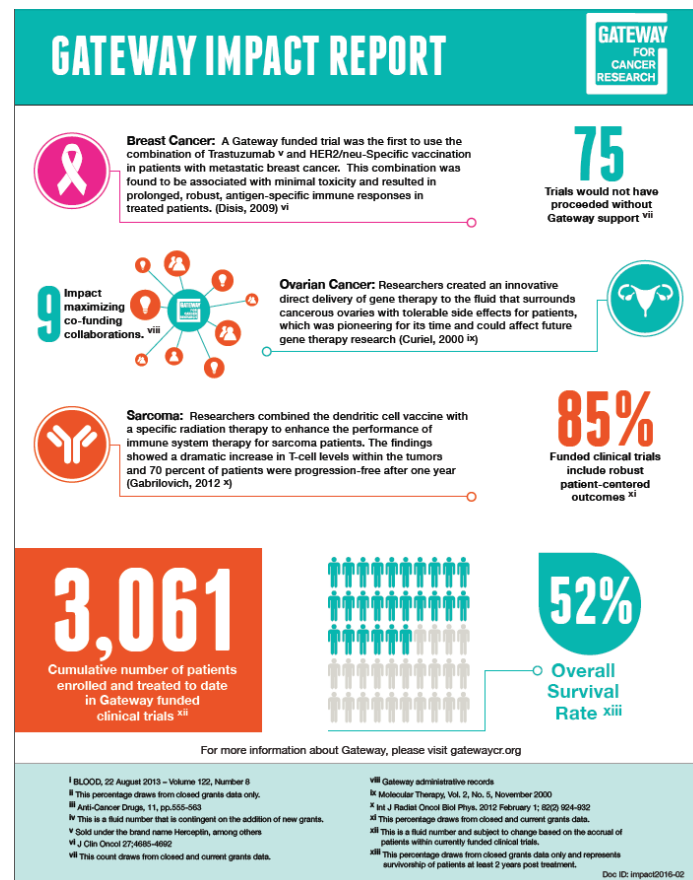


Gateway's Impact Framework: What has been the impact of the funding?

| Gateway Impact Dashboard (Cumulative) ©2017 Gateway for Cancer Research | | | | | | | | |
|--|---|---|--|------------|---|--|-----------------|---|
| Pillar 1: Patients Have a Voice | | | Pillar 2: Patients Feel Better & Live Longer | | | Pillar 3: Patients Contribute to Overcoming Cancer in the Future | | |
| Outcomes | Indicators | | Outcomes | Indicators | | Outcome | Indicators | |
| Amplify patient voice in Gateway's decision-making | N/A | # of patient voices engaged in shaping Gateway's priorities | Improve quality of life | 62% | % of patients seeing a reduction in interference with life between design stage and trial stage | Create a shared sense of urgency | 9 | # of unique funding collaborations and partnerships |
| | N/A | # of caregiver and family voices engaged in shaping Gateway's priorities | | N/A | % of patients gaining hope for the future | | 70% | % of Gateway supported trials that progress to next phase of research |
| | N/A | # of stakeholder questions addressed in Gateway-funded research | | 31% | % of patients maintaining or improving life quality | | N/A | # of Gateway supported trials that reach clinical practice |
| Increase centrality of patient voice for Gateway supported trials | 10 | # patient representatives involved in Gateway's decisionmaking | Improve health outcomes | 3,222 | # of patients accrued | Improve the standard of care via transformative discoveries | 75 | # trials that would not have proceeded without Gateway support |
| | 83% | % of funded trials that include robust patient-centered outcomes | | 11% | % of patients whose cancer responds partially to treatment | | \$13,699,743.41 | \$ additional dollars leveraged by Gateway investments |
| | 6% | % of funded trials that incorporate consultation with patient representatives | | 17% | % of patients who experience complete response or remission | | N/A | # new NCCN treatment guidelines catalyzed by Gateway-supported research |
| | | | | 25% | Progression-free survival rate (optional) | | | |
| | | | | 52% | Overall survival rate (optional)† | | | |
| Impact Dashboard Key: | | | | | | | | |
| Source of Data: | Gateway GMS system capture of grant recipient data, including: application, semi-annual, final, and follow-up reports. Closed grants data is the only data included for all the indicators in Pillar 2 (with the exception of #Patients Accrued), and the second indicator in Pillar 3. Closed and currents grants data is included for the fifth indicator in Pillar 1, and the fourth and fifth indicators in Pillar 3. Patient voice data is collected by Marketing team through website and provided to research staff members. The fourth indicator in Pillar 1 and the first indicator in Pillar 3 are collected from Administrative Records outside of the GMS. Shaded Areas Denote Key Indicators | | | | | | | |
| N/A: | Used when data is inaccurate or not yet available from 2015 launch of impact framework (a.k.a. "data not yet available"). | | | | | | | |
| †: | This percentage draws from closed grants data only and represents patients alive at least 2 years post treatment. | | | | | | | |
| Date: | Snapshot from 2.9.2017 | | | | | | | |



Gateway's Global Impact Report





Lessons Learned & Feedback From the Field

Lessons

Grant data is **complex and nuanced**

Systematic record-keeping is critical to measuring and reporting on impact

Complete picture of impact requires **looking back and looking forward**

Impact measurement and reporting is **fluid**

Continuous improvement is organic, ongoing, incremental, and informed

Impact measurement is **not perfect, yet, it is compelling** to Gateway donors

Feedback

Impact framework is challenging **investigators** to listen to the patient's voice in ways they have not before

Gateway's focus on lifting up patient voice is challenging **institutions** to consider funder requests to speak with patients directly, if interested, and contingent on patient consent

Comments from current Gateway grantees:

- *"Gateway is unique in its interface of clinical trial research with that of health related quality of life of patients in their clinical trials. This is **an opportunity to measure both qualitative as well as quantitative** (such as disease status and overall survival) **outcomes**."*
- *"Gateway is ultimately - patient centered. They listen to the patient and their **funding is focused on the issues that concern patients**."*



Concluding Remarks

To learn more about Gateway, visit gatewaycr.org.

To access Gateway's online Grants Management System (GMS), visit gatewaycr.fluidreview.com/

To keep in touch or request additional information, please contact me at 847-342-7443 or Domarina.Oshana@gatewaycr.org. I'm also happy to connect on LinkedIn: <http://www.linkedin.com/in/domarinaoshana>.

To download takeaways, click on the following links:

- **Public Articulation** of Gateway's Impact Framework and **Global Impact Report**: gatewaycr.fluidreview.com/res/p/GatewayImpact/
- **Gateway's Funding Guidelines**: <https://gatewaycr.fluidreview.com/res/p/FundingGuidelines/>
- **Gateway's FAQ for Grant Applicants**: <https://gatewaycr.fluidreview.com/res/p/FAQ/>



Time for Q & A

Thanks for
participating in
this session!

Happy to
answer any
questions.

