# GENOMICS IN SOCIETY
# **Expert Panel**

## Integrated GE$^3$LS Research Review Report

September
**2018**

GenomeCanada

GLOBAL CHALLENGES ✦ GENOMIC SOLUTIONS

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# GENOMICS IN SOCIETY
# **Expert Panel**

## Executive summary

Genome Canada's mandate focuses on genomics; however, it not only invests in scientific advances and technological developments, but also supports research that is generally conducted by social scientists, legal scholars and humanities scholars who investigate the implications of genomics in society. Known as GE$^3$LS research (an acronym that historically referred to genomics and its ethical, environmental, economic, legal and social aspects), it represents an investment of $121 million to date. Such investment was made through three funding models: integrated GE$^3$LS research, which is being reviewed in this Report; large-scale standalone GE$^3$LS research projects; and translational networks.

Genome Canada is recognized as a "world leader" in GE$^3$LS research. However, in Genome Canada's 2014 Five Year Evaluation, it was recommended that *the effectiveness of integrated GE$^3$LS in facilitating the translation of genomics research* be assessed. This task has been assigned to the ad hoc Genomics in Society Expert Panel (the Expert Panel), established by Genome Canada's Science and Industry Advisory Committee (SIAC).

## Mandate and Methodology

The Expert Panel's mandate was to undertake a review of Genome Canada's integrated GE$^3$LS research to understand how it is being conducted and whether it is achieving the stated objective of facilitating the uptake of genomic-based applications, and to identify factors that contribute to or hinder this success. In doing so, the Expert Panel was asked to produce the following three key deliverables:

1. A definitional framework for integrated GE$^3$LS research in Canada.

2. The identification of key indicators of success; factors that contribute to the successful integration of GE$^3$LS research; factors that may inhibit success; and strategies for removing these barriers.

3. An assessment of the effectiveness of integrated GE$^3$LS research in contributing to the overall uptake of genomic-based applications.

Complementary methods were relied on to gather data that would inform the Expert Panel's deliberations and recommendations. Genome Canada staff reviewed documents (e.g. applications, final reports) related to nine projects and conducted interviews of nine Project Leaders and eight GE$^3$LS Leads, as well as six users of the research and four members of

Research Oversight Committees for a total of 26 separate interviews. Eight of these projects were developed as case studies selected from Large-Scale Applied Research Project (LSARP) competitions held between 2008 and 2015, which span several sectors.

Genome Canada staff also undertook a survey of peer reviewers who reviewed LSARP applications in the four most recent competitions (2012, 2014, 2015, 2017).

In addition, Genome Canada staff carried out telephone interviews with stakeholders of the Genomics Enterprise, including 10 Genome Centre staff, one Genome Canada staff and one external consultant with expertise in Genome Canada's competitions.

Informed by the evidence and discussions amongst the Expert Panel over the course of several meetings, which resulted in a consensus amongst all members, the Expert Panel offers four recommendations in response to the key deliverables.

## Recommendations

### Recommendation 1: Affirm the Value and Vision of Integrated GE³LS Research

The Expert Panel's first recommendation is a strong endorsement of the value of GE³LS research and the integrated model. The Expert Panel determined that the research community and other stakeholders view Genome Canada as a leader regarding GE³LS research and believes it should maintain this role and continue to support such research.

Additionally, the Expert Panel believes that, despite some misunderstanding about the GE³LS acronym, the term should continue to be used to refer to this unique research approach. However, the Expert Panel believes the term GE³LS should be interpreted broadly to refer to "research into the implications of genomics in society."

The Expert Panel recognizes that integrated GE³LS research has evolved and that a definitional framework must place the emphasis on researchers with diverse disciplinary backgrounds collaborating to conduct applied research that potentially will result in genomic-based applications that can generate benefits.

**THEREFORE, THE EXPERT PANEL RECOMMENDS:**

Genome Canada should reaffirm its commitment to the value of research into the implications of genomics in society by strengthening its support for the integration of GE³LS research in large-scale projects to foster the responsible and effective development and uptake of genomic-based applications.

Recognizing that the GE³LS acronym has historic and ongoing relevance, the Expert Panel recommends that it be retained. Nevertheless, Genome Canada should promote a broader interpretation of GE³LS as "research into the implications of genomics in society" that extends beyond the narrow focus on topics and/or disciplines that make-up the acronym and should encourage innovation in GE³LS research strategies and methods to help accelerate the translation of genomics solutions into benefits to society.

To ensure that the broader interpretation of integrated GE³LS research is better understood, Genome Canada should adopt a definitional framework that emphasizes the following elements:

- Adopting a team-based approach where researchers with diverse expertise, using a variety of research strategies and methodologies, collectively contribute to a broader understanding of the scientific problem;
- An investigation of factors that may facilitate or hinder the acceptance and uptake of the genomic-based application(s); and
- Provision of evidence that may be useful to inform and help implement changes in policy or practice related to its use.

The Expert Panel further recommends that Genome Canada undertake a targeted communication initiative to advance these objectives within 12 months of adopting these recommendations.

Recommendation 1 fulfills Deliverable 1 by presenting a definitional framework that supports a broad interpretation of integrated GE³LS research.

## Recommendation 2: Enhance Implementation of the Integrated GE³LS Research Vision in Large-Scale Projects

In developing its second recommendation the Expert Panel identified factors and elements of the LSARP competition process that may contribute to or hinder successful integration of GE³LS research and the uptake of genomic-based applications.

The Expert Panel concluded that all elements of the competition process – the development of the team, the preparation of applications, the review process and the execution of the research – must reinforce a clear and common understanding of the nature of integrated GE³LS research to increase the likelihood of achieving the desired outcomes.

**THEREFORE, THE EXPERT PANEL RECOMMENDS:**

Genome Canada should review its competition processes used to support funding of large-scale projects to address perceived or identified barriers to selecting strong integrated GE$^3$LS research. Program requirements, activities to assist team formation and research development, review criteria and processes, the selection of peer reviewers and members of Research Oversight Committees are amongst the key elements that must be aligned with the definitional framework suggested in Recommendation 1, particularly to reflect the diversity of research expertise involved in projects, and to account for the complexity of translating (genomics and GE$^3$LS) research results into tangible benefits.

The Expert Panel strongly encourages Genome Canada to take all appropriate actions at the earliest opportunity, starting with the 2018 LSARP competition, and to be completed over the next two competitions.

This second recommendation responds to Deliverable 2, regarding key indicators of success and factors that contribute to, or inhibit successful integration, along with strategies to remove barriers.

## Recommendation 3: Enhance Capacity to Conduct and Support Integrated GE$^3$LS Research

Through this Review, the Expert Panel identified two distinct yet interdependent aspects of capacity that deserve attention: the capacity within the research community **to conduct** integrated GE$^3$LS research, and the Genomics Enterprise's capacity **to support** integrated GE$^3$LS research. Recognizing that integrated GE$^3$LS research is a unique model, targeted actions will be required to enhance capacity in each of these two areas.

**THEREFORE, THE EXPERT PANEL RECOMMENDS:**

To strengthen integrated GE$^3$LS research, Genome Canada should undertake the following actions to increase capacity:

1. Build capacity to conduct GE$^3$LS research as part of large-scale projects:

   Genome Canada should commit to increasing the breadth of researchers pursuing GE$^3$LS research as part of large-scale projects, including early career researchers, including through the development of training opportunities.

   Genome Canada should seek ways to enhance the collaborations with partners that support social sciences and humanities research and other interdisciplinary research, including universities, federal granting councils and other national or international stakeholders.

2. Build capacity to support GE³LS research leadership to enhance integration in large-scale projects:

   Genome Canada should reinstate a national senior position whose role would include long-term visioning and oversight of the GE³LS research program and, in the short term, supporting the timely execution of the recommendations set out in this Report.

   Genome Canada should provide targeted resources to support the Genome Centres' efforts to enhance integrated GE³LS research as part of large-scale projects. Where appropriate, Genome Canada should assist in the coordination of such work, or in the development of tools or other material that facilitates it.

By proposing actions related to those who conduct research and those who support it, Recommendation 3 also addresses Deliverable 2 about factors that contribute to or inhibit successful integration of GE³LS research in LSARPs.

## Recommendation 4: Accountability for the Implementation of the Recommendations

The Expert Panel's fourth recommendation focuses on accountability, in two regards. First, the Expert Panel believes the recommendations presented in this Report should be discussed by the wider stakeholder community before Genome Canada takes further action. Genome Canada should be accountable to stakeholders and maintain transparency in the decisions it will make in relation to these recommendations, thereby following an accountability pathway in the implementation of the recommendations.

Secondly, the Expert Panel acknowledges the importance of demonstrating the value and impact of GE³LS research and encourages the development of key performance indicators as part of the evaluation strategy for LSARP competitions.

### THEREFORE, THE EXPERT PANEL RECOMMENDS:

Implementation and evaluation go hand in hand. The following actions are called for:

1. Recognizing the interest in this Review, the Expert Panel encourages Genome Canada to undertake a comprehensive consultation with the research community, Genome Centres and other stakeholders on the findings and recommendations of the Expert Panel. Following the consultation, the results should be shared with the Genome Canada Board through SIAC to help inform decision-making. In this way, Genome Canada would follow an accountability pathway for the implementation of this Expert Panel's recommendations.

2. Genome Canada should strive to assess the overall value of integrated GE$^3$LS research, its outcomes and its impact within Canada through the development and application of key performance indicators that capture the diversity of this research and its translational pathways. This should be part of an overall strategy for longitudinal performance evaluation.

The Expert Panel encourages Genome Canada to initiate these actions in partnership with Genome Centres, within 12 months of adopting these recommendations.

Recommendation 4, through its focus on accountability and evaluation, responds to Deliverable 3 regarding an assessment of the effectiveness of integrated GE$^3$LS research in contributing to the uptake of genomic-based applications.

## Conclusion

The three key deliverables outlined in the Expert Panel's mandate are presented through four recommendations, to assist Genome Canada's Board of Directors in its decisions related to GE$^3$LS research and its integration in large-scale, applied genomics projects.

Moreover, the Expert Panel notes that, even though this Review focused on integrated GE$^3$LS research, there also was evidence that diverse funding structures are required to ensure a more comprehensive understanding of the full range of implications of genomics in society. Therefore, Genome Canada should maintain a suite of research funding models to investigate the implications of genomics in society.

# Acknowledgements

Genome Canada is grateful to the individuals listed below who, as members of the Genomics in Society Expert Panel, conducted this Review of Integrated GE$^3$LS Research:

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**Genome Canada Science and Industry Advisory Committee members at the time the Review was conducted*

The work of the Expert Panel benefited from the contributions of Dr. Cindy Bell (Executive Vice President, Genome Canada, Jillian McGivern (Research Analyst, Genome Canada), Dr. Samantha Evans (Evaluation Consultant) and Karine Morin (GE$^3$LS Consultant), who carried out data collection and analysis, drafted the Report and supported all aspects of the Review. Dr. Karen Dewar (Director, Genomics Programs) and Dr. Karl Tibelius (Vice President, Genomics Programs) at Genome Canada provided information regarding the competitions; the GE$^3$LS Leads and other staff at the regional Genome Centres assisted throughout, helping identify case studies and communicating with individuals who participated in interviews related to them; and all interview participants gave time and valuable insights regarding their experiences with Genome Canada, integrated GE$^3$LS research and competitions. The Expert Panel is grateful for all this support.

# Introduction

A unique feature of Genome Canada's brand and focus since its inception in 2000 has been its commitment to enable the integration of social science and humanities perspectives into the genomics research it supports.

For example, Genome Canada's original 2000 funding agreement with the Government of Canada included the following expectation:

> Ensuring leadership in the areas of social, environmental, ethical and legal issues related to genomics by organizing intellectual resources and to effectively communicate genomics to the public, helping Canadians understand the relative risks and rewards of genomics.

This became known by the acronym "GELS." Unlike its American counterpart "ELSI" that referred to Ethical, Legal and Social Implications, Genome Canada's GELS program began with two "E" components: ethical and environmental issues.

By the time of the 2004 funding agreement, "economics" was added and the formula-like acronym "GE$^3$LS" was established, which has remained ever since. The objective for GE$^3$LS was described as:

> The assumption of leadership in the area of ethical, environmental, economic, legal, social and other issues related to Genomics research (GE$^3$LS) and the communication of the relative risks, rewards and successes of Genomics to the Canadian public.

In 2012, the wording of the objectives in Genome Canada's agreement with the Government of Canada was significantly overhauled. The objective relating to GE$^3$LS was separated into two new ones:

> Enhance the impact of genomics by transforming knowledge of the ethical, environmental, economic, legal and social challenges and opportunities into sound policies and practices.
>
> Enhance the recognition of the value of genomics by increasing stakeholder appreciation of genome science, its applications and its implications.

Genome Canada responded to this new vision by joining these objectives under a broader Genomics in Society umbrella that includes GE$^3$LS research as well as other communication and stakeholder engagement activities to inform science, technology and innovation related to genomics and its responsible development and application.

## What is GE³LS Research?

From Genome Canada's inception, it was clear that genomics deserved careful examination from the perspective of the social sciences and humanities, as it was having a transformative effect on the life-sciences, and its technological applications were increasingly impacting many sectors of the economy and facets of society. GE³LS research then, can be understood broadly as studies that primarily use the diverse methods from the social or behavioural sciences, law and humanities to explore issues related to genomics. It is not strictly limited to disciplines that make up the acronym but rather encompasses all those that rely on analytical, qualitative and quantitative methodologies to investigate genomics across the life sciences and the implications these innovations have on society, thereby producing knowledge to inform responsible genomics research, accelerate its translation and enable the uptake of applications and establishing an evidence base to develop and implement new practices and policies.

## GE³LS Research as Part of LSARP Competitions

One of Genome Canada's main investments, and the program that features GE³LS research, is the Large-Scale Applied Research program. Through each Large-Scale Applied Research Project (LSARP[1]) competition, Genome Canada funds multi-million-dollar applied research projects that aim to advance genomics research and translate findings into applications that are adopted by users.

GE³LS research was funded in Genome Canada's first large-scale competition, Competition I, in 2000. Starting with Competition III, in 2004, all projects that were not exclusively focused on GE³LS research were required to consider the GE³LS aspects of their research, and as appropriate, to develop a plan to address them.

Through the LSARP competitions, Genome Canada now funds three models of GE³LS research:

- **Integrated GE³LS research**
  GE³LS research as described above, but specifically embedded within large-scale genomics research projects. The integrated GE³LS research component should be shaped by, and help shape, the overall project by investigating key factors that may facilitate or hinder the uptake of the genomic-based application(s) being developed by the project. It should support collaboration between genomic scientists and GE³LS researchers throughout all aspects of the research project.

- **Large-scale standalone GE³LS research projects**
  These projects investigate significant challenges and/or opportunities related to genomics research and related innovations in the sector(s) targeted in a competition. It is expected that large-scale standalone GE³LS research projects demonstrate active engagement with the genomics scientific community in the planning of the research and its conduct.

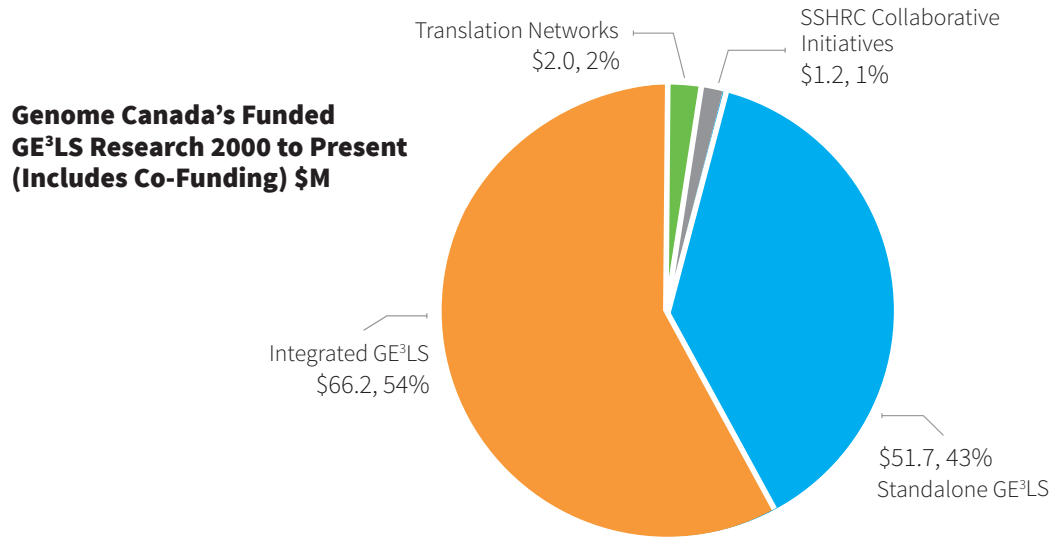
[1] See also Appendix One: Glossary.

- **Translational networks**
  These networks bring together researchers participating in separately-funded projects to collectively investigate factors affecting the advancement, adoption, evaluation and governance of genomics in relation to a specific topic or sector. The program aims to strengthen the connections between researchers, users and other stakeholders to address aspects of genomics research and its applications that span the sector, beyond individually-funded projects.

While all three models are worthy of a comprehensive review, the Expert Panel focuses on integrated GE³LS research, in response to the 2014 Genome Canada Five-Year Review, which recommended *that the effectiveness of integrated GE³LS in facilitating the translation of genomics research* be assessed.

Since Genome Canada was established, there has been a total investment in GE³LS research of CDN$121 million (i.e. Genome Canada contributions as well as co-funding). As noted in Figure 1, 54% of this investment (CDN$66.2 million) has supported integrated GE³LS research in large-scale projects, 43% (CDN$51.7 million) has supported large-scale standalone GE³LS projects and 2% (CDN$2 million) has supported a translational network. An additional 1% (CDN$1.2 million) investment has been made outside the LSARP program, through a joint initiative with the Social Sciences and Humanities Research Council (SSHRC) that was initiated in 2016, to build capacity among social scientists or humanities scholars to conduct GE³LS research.

**Figure 1: Total Funding (Genome Canada and Co-Funding) of GE³LS Research Activities, 2000-2018**



# Mandate of the Expert Panel

In November 2017, Genome Canada through its Science and Industry Advisory Committee (SIAC) convened an ad hoc panel of experts to review integrated GE$^3$LS research in the LSARP competitions, in response to Genome Canada's 2014 Five Year Evaluation,[2] which recommended that the effectiveness of integrated GE$^3$LS research in facilitating the translation of genomics research be assessed. This Review is also intended to inform any subsequent evaluation of the broader Genomics in Society (GiS) portfolio.

The Expert Panel's mandate was to undertake a review of Genome Canada's integrated GE$^3$LS research to understand how it is being conducted and whether it is achieving the stated objective of facilitating the uptake of genomic-based applications, and to identify factors that contribute to or hinder this success. The Expert Panel was to produce the following three key deliverables:

1. A definitional framework for integrated GE$^3$LS research in Canada.

2. Key indicators of success; factors that contribute to the successful integration of GE$^3$LS research; factors that may inhibit success; and strategies for removing these barriers.

3. An assessment of the effectiveness of integrated GE$^3$LS research in contributing to the overall uptake of genomic-based applications.

Members of the Expert Panel share a mix of research expertise related to genomics and its impact on society. These members acted in an independent capacity rather than as representatives of their disciplines or organizations and were free of any business or other relationship that could materially interfere with the exercise of their independent judgment. Three, including the Chair, were members of SIAC at the time the Review was conducted. The eight members are from Canada, the United States and the United Kingdom.

[2] https://www.genomecanada.ca/sites/genomecanada/files/pdf/en/five-year-evaluation-2014.pdf. See also Appendix Five: Previous Evaluations of GE$^3$LS Research Progress.

## Methodology

The Expert Panel Review consisted of three core activities, which were designed to produce three key deliverables as summarized in Table 1.[3]

**Table 1: Core Activities and Expected Key Deliverables**

| Core Activities | Key Deliverables |
|---|---|
| **Review how integrated GE³LS research has been undertaken across Canada.**<br>**Key question:**<br>How is integrated research defined and actioned by key stakeholders? | A definitional framework for integrated GE³LS research in Canada. |
| **Identify examples of successes, best practices and impediments of integrated GE³LS research in large-scale research projects.**<br>**Key questions:**<br>• What does success look like for integrated GE³LS research, within projects and/or within competitions and in the aggregate at the national level?<br>• What are the key indicators of best practice in developing integrated GE³LS research?<br>• How do Genome Canada's processes, guidelines and criteria affect selecting for success in integrated GE³LS research? | Identification of: key indicators of success; factors that contribute to the successful integration of GE³LS research; factors that may inhibit success; and strategies for removing these barriers. |
| **Review outcomes from a sample of integrated GE³LS research to assess how effective they are in supporting the uptake of genomic-based applications.**<br>**Key question:**<br>To what extent has integrated GE³LS research been effective in translating research results into practice and policy and in supporting the uptake of genomic-based applications? | An assessment of the effectiveness of integrated GE³LS research in contributing to the overall uptake of genomic-based applications. |

The Review focuses on integrated GE³LS research funded since the Applied Genomics Research in Bioproducts or Crops Competition in 2008, and includes some limited data related to the 2017 Large Scale Applied Research Project Competition – Genomics and Precision Health.

[3] See also Appendix Two: Panel Review Methodology.

Key data sources were:

- **Case studies of projects funded from 2008 to 2015:**
  - Document review of large-scale project applications and reports (final reports and/or interim reports, if projects were still in progress) from selected projects.
  - Semi-structured interviews conducted separately with nine Project Leaders/Project Co-Leaders,[4] eight GE$^3$LS Leads/Co-Leads, four members of Research Oversight Committees and six users of the research, for a total of 26 individuals involved in the selected LSARPs[5] (hereinafter "project interviews").

- **Genomics Enterprise interviews:**
  - Semi-structured interviews with stakeholders of the Genomics Enterprise, including 10 Genome Centre staff, one Genome Canada staff and one external consultant with considerable experience with LSARP competitions.

- **Peer Reviewer survey:**
  - A survey of peer reviewers (sent to 123 peer reviewers, 40 of whom responded, for a 32.5% response rate) who have reviewed applications in the four most recent LSARP competitions (2012, 2014, 2015, 2017).

- **Review of Genome Canada documentation:**
  - Genome Canada's performance and prior evaluations, competition processes, RFAs and evaluation criteria across competitions.[6]

The Review collected primarily qualitative evidence with open-ended questions, although some quantitative data were also obtained, particularly through the survey.

Genome Canada staff carried out the data collection and presented the evidence to the Expert Panel over the course of approximately five months. The Expert Panel met several times by teleconference to review materials, assess the evidence, develop recommendations and finalize the Report drafted by Genome Canada staff.

The recommendations were developed in an iterative manner: using background information along with data collected through the early phase of the Review, preliminary recommendations were drafted a few months after the Expert Panel was convened. Once all the data were collected and analyzed over the next several months, the recommendations were refined into their final version, with the unanimous support from the members of the Expert Panel.

[4] Due to availability for interviews and/or researcher succession on a project, a Project Leader or Project Co-Leader and GE$^3$LS Lead or GE$^3$LS Co-Lead, may have been interviewed for a case study. However, both types will be referred to as Project Leaders and GE$^3$LS Leads unless specifically differentiated from the original Project Leaders and GE$^3$LS Leads.

[5] One selected project was not developed into a case study because only the Project Leader was interviewed, but not the GE$^3$LS Lead. Evidence from the project was used, as appropriate, in the overall analysis.

[6] See also Appendix Four: Descriptions and Criteria of GE$^3$LS Research in the LSARP Competitions (2008 – 2017)

## Recommendations and Key Findings

To address the mandate, the Expert Panel considered the integrated GE$^3$LS research that was conducted as part of the eight case studies developed for this Review,[7] which can be broadly described as follows:

- **Research into the values and perceptions of various stakeholders or users**
  This includes studies that reveal or inform the attitudes throughout society (e.g. from providers, patients, innovators, investors, etc.), specifically their decisions or actions either to adopt or resist a new technology. This research seeks to understand how various risks (e.g. legal, economic, environmental, moral) are understood and how they are assessed in the context of adopting or not a new genomic-based tool or in developing a new practice or policy related to the use of such a tool.

- **Research related to the commercialization of genomic-based applications**
  This includes understanding how existing legal and regulatory regimes affect the market penetration of new products, such as market approval, trade restrictions, or regulatory burden

- **Research related to implementation**
  This includes research into the necessary conditions or support mechanisms required for a new technology to be used safely and effectively; this often includes investigating means to disseminate the new technology, and educate and communicate changes related to its adoption.

- **Research on economic factors**
  This includes research on the development and use of models that account for key variables and can help predict choices, socio-economic value and related assessments.

This Report is organized according to the four recommendations, which together address the Expert Panel's mandate and deliverables:

- **Recommendation 1:**
  Affirm the Value and Vision of Integrated GE$^3$LS Research

- **Recommendation 2:**
  Enhance Implementation of the Integrated GE$^3$LS Research Vision in Large-Scale Projects

- **Recommendation 3:**
  Enhance Capacity to Conduct and Support Integrated GE$^3$LS Research

[7] One selected project was not developed into a case study because the GE3LS Lead was not available for an interview. Evidence from the project (including findings from interviews with the Project Leader and a user of the research) was used, as appropriate, in the overall analysis.

- **Recommendation 4:**
  Accountability for the Implementation of the Recommendations

Each recommendation is followed by a discussion of the evidence that most directly relates to it.

Overall, the Expert Panel acknowledges that enhancing integrated GE$^3$LS research has been an ongoing process and believes the breadth and depth of the Review should add momentum to these efforts. Where appropriate, the recommendations also include specific timelines by which they should be undertaken, to ensure that proposed actions are taken in a timely fashion.

## Recommendation 1: Affirm the Value and Vision of Integrated GE$^3$LS Research

Genome Canada should reaffirm its commitment to the value of research into the implications of genomics in society by strengthening its support for the integration of GE$^3$LS research in large-scale projects to foster the responsible and effective development and uptake of genomic-based applications.

Recognizing that the GE$^3$LS acronym has historic and ongoing relevance, the Expert Panel recommends that it be retained. Nevertheless, Genome Canada should promote a broader interpretation of GE$^3$LS as "research into the implications of genomics in society" that extends beyond the narrow focus on topics and/or disciplines that make-up the acronym and should encourage innovation in GE$^3$LS research strategies and methods to help accelerate the translation of genomics solutions into benefits to society.

To ensure that the broader interpretation of integrated GE$^3$LS research is better understood, Genome Canada should adopt a definitional framework that emphasizes the following elements:

- Adopting a team-based approach where researchers with diverse expertise, using a variety of research strategies and methodologies, collectively contribute to a broader understanding of the scientific problem;
- An investigation of factors that may facilitate or hinder the acceptance and uptake of the genomic-based application(s); and
- Provision of evidence that may be useful to inform and help implement changes in policy or practice related to its use.

The Expert Panel further recommends that Genome Canada undertake a targeted communication initiative to advance these objectives within 12 months of adopting these recommendations.

The Expert Panel's first recommendation is a strong endorsement of the value of GE³LS research and the integrated model. The Expert Panel found that key stakeholders, including researchers, peer reviewers, users and Genome Centres strongly believed that Genome Canada should continue to support research into the implications of genomics in society, including through the integrated GE³LS research model.

To ensure that researchers and other stakeholders better understand the purposes of GE³LS research, as well as its integration into large-scale projects, the Expert Panel proposes a clearer, broader interpretation of the acronym, and provides the first key deliverable – a new definitional framework. The evidence discussed below, therefore, focuses on the value and the vision of integrated GE³LS research.

## A. The Value of Integrated GE³LS Research

The integration of GE³LS research in large-scale genomics projects is premised on the belief that it can facilitate the uptake of genomics-based applications by addressing specific translational issues related to these applications. In the LSARP competitions considered under the Review, Genome Canada specifically required that the integrated GE³LS research facilitate the translation of the genomics research, which can result in social or economic benefits arising from the uptake, adoption, or adaptation of products, processes and policies, as well as public engagement and awareness. It is this aspect of integrated GE³LS research that the Genome Canada 2014 Five Year Evaluation recommended be assessed.

However, in addition to such outcomes (hereinafter referred to as "ultimate" outcomes), the Review identified other benefits of integrating GE³LS research in large-scale genomics projects, which typically occurred as projects were being conducted (hereinafter referred to as "intermediate" outcomes). Each are examined below.

### i. Value in Facilitating the Translation and Uptake of Genomics Research (Ultimate Outcomes)

An assessment of the effectiveness of integrated GE³LS research in contributing to the uptake of genomic-based applications, was one of the Expert Panel's key deliverables.

To address this deliverable, the Expert Panel relied on the case studies and found the following examples of the impact of integrated GE³LS research:

- GE³LS researchers involved in a project addressing plant adaptation to climate change explored factors that would influence the uptake of practices informed by genomic analyses. These findings were directly informative to a provincial government working group developing a new framework and technical guidelines on such adaptation strategies.

- As part of a project using diverse plant species, the GE³LS researchers considered developments under the Convention on Biological Diversity and the associated Nagoya Protocol related to access to genetic resources and equitable sharing of benefits (ABS). Finding that the origin of plant species was a key factor in determining access to these resources and the benefit-sharing obligations between users and providers, and that several targeted plant species originated from countries with strong ABS laws, the GE³LS researchers were able to advise the genomics researchers as to these implications when selecting plants for their research.

- GE³LS researchers, through their user engagement, were able to determine that economic considerations were not the sole decision factor related to uptake, but that regulatory issues would need to be clarified and best practices developed for users to take an interest in the new technology (animal health diagnostic). Overall, they helped translate the genomic technology into a usable tool.

- When a trade ban was unexpectedly imposed on exports of a crop that was being studied by a funded project, the GE³LS researchers were quickly able to help assess the economic impact. In addition, their planned research on intellectual property rights provided clarity to genomics researchers on the challenges that products derived from the crop and aimed at the health sector would likely face, in contrast to greater freedom to operate in the agricultural sector.

- In a project focused on precision health, one of the key GE³LS research activities was the development of a communication toolbox, which is being used by health professionals to explain risk stratification to their patients.

- GE³LS research in another precision health project helped guide the development of clinical trial protocols that would address ethical issues regarding the patient population.

## Translational Pathways to Achieve Ultimate Outcomes

In these case studies, facilitating the uptake of genomic-based applications follows three different pathways: commercialization, policy (or regulatory) changes and changes in practice. Interviews with Project Leaders and GE³LS Leads highlighted that conducting GE³LS research to align with these pathways presents different challenges.

- **Commercialization**
  In projects where teams were seeking to commercialize the research, Project Leads often looked to the GE³LS research to inform business decisions, such as whether there is potential for spinoff companies. This was considered as potentially blurring the distinction between GE³LS and the provision of

business services. Additionally, when GE³LS research uncovers barriers that cannot be mitigated during the project, this raised concerns that GE³LS is ineffective in facilitating the uptake of the applications.

- **Policy and regulatory change**
  Interview participants involved in projects that sought to inform policy or regulatory change emphasized some of the challenges, such as policy timing (where an issue needs to be a government priority for policy-makers to take a close interest) and the importance of establishing relationships of trust with policy-makers, an activity that often needs to pre-date a project, or which ultimately occurs after its completion. Overall, affecting policy or regulatory change through a single research project is an almost unattainable goal, but GE³LS Leads nevertheless believed in the value of providing information that helps policy-makers or regulators learn of advances in genomics that bear on their mandate. When the timing has been right, interview participants noted that users were keen to rely on the research to inform policy or regulatory development.

  Regarding policy or regulatory change, Genome Centre staff noted that unless researchers had a solid understanding of the relevant regulatory or policy context, they were unlikely to succeed in affecting change that could facilitate translation and uptake. They further explained that while policy and regulatory change is one of the expected outcomes from integrated GE³LS research, there is little expertise within the Genome Centres to assist in the development of such research. Genome Centres expressed a need for national leadership, potentially facilitated by Genome Canada, to provide expertise and undertake the groundwork on key policy or regulatory issues to support researchers. Alternatively, some believed such issues are best addressed through large-scale standalone GE³LS research projects or through translational networks.

- **Practice change**
  Interviews with GE³LS Leads noted that affecting changes in practice by users is also challenging; changes appear more likely to occur after prolonged engagement and with a growing understanding of the users' needs, and conversely, an understanding by users as to the potential issues that can be addressed through research.

  Where changes in practice had occurred, GE³LS research was very closely informed by the state of the industry and gaps that needed to be filled, and when there was a close working relationship with individuals who have the leadership to initiate change or organizations that have the authority to enact changes (e.g. set new standards). In such instances, users often became actively engaged in the project, and the outputs appeared to have provided timely, practical information that was of value to them.

## ii. Added Value of Integrated GE³LS Research (Intermediate Outcomes)

In addition to integrated GE³LS research being an effective means to facilitate the uptake of genomic-based applications along various translational pathways (ultimate outcomes), Project Leaders and GE³LS Leads identified several other beneficial outcomes related to the integration of GE³LS research, which added value to the projects (intermediate outcomes):

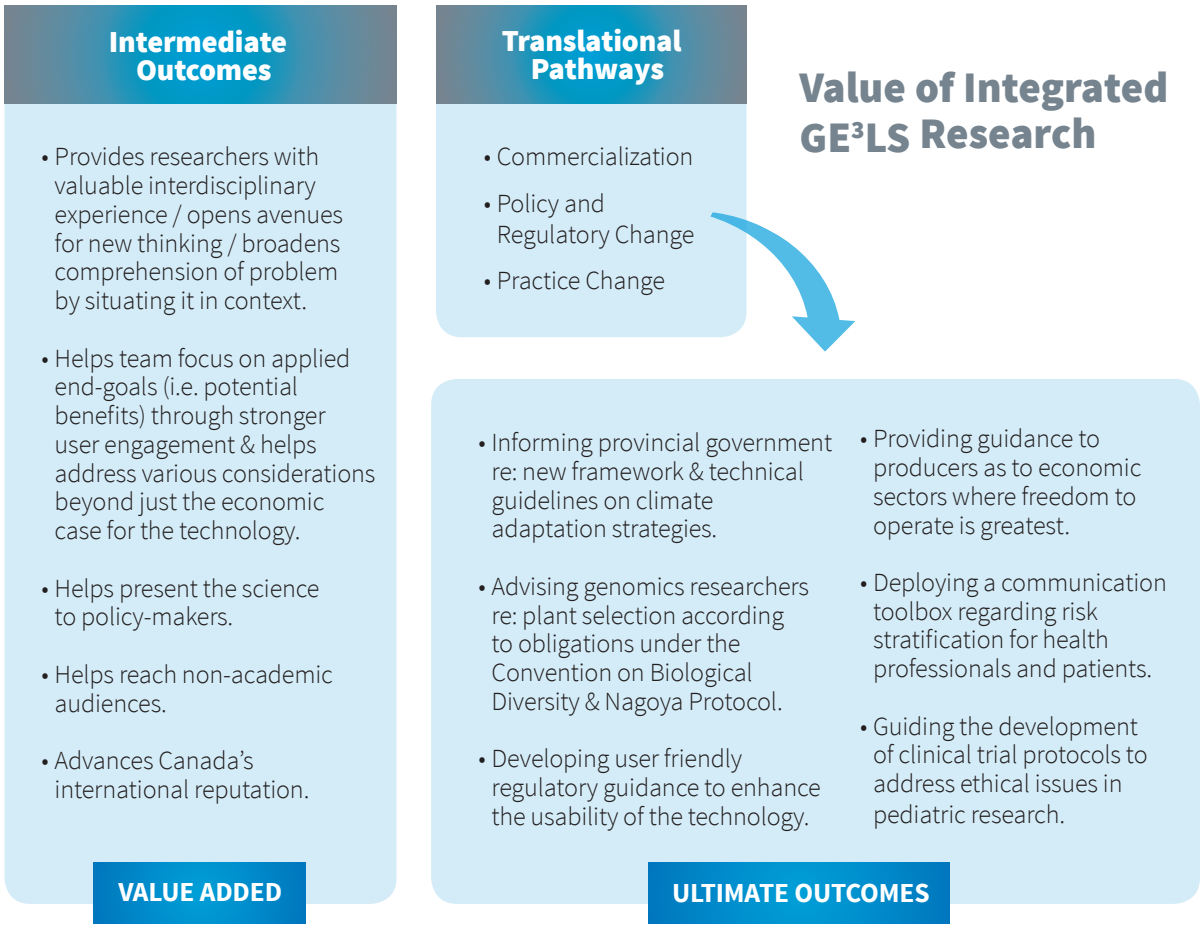
- Providing researchers with valuable interdisciplinary experience that opens avenues for new thinking and innovative research approaches and that broadens the comprehension of the scientific problem by situating it beyond the scientific context and into a larger societal perspective.
- Helping the team focus on applied end-goals (i.e. the potential benefits of the research), including through stronger user engagement. This also entailed helping teams address various considerations relevant to users, beyond the economic case.
- Helping present the science to policy-makers in ways that can help them understand its relevance and applicability.
- Helping reach audiences beyond academic circles by ensuring that the scientific knowledge was usable and its dissemination broad.
- Facilitating communication to the public by genomics scientists through activities such as Café Scientifique,[8] which can foster the acceptance of genomic research.
- Advancing Canada's international standing in genomics research. Some GE³LS Leads have contributed considerable expertise at the international level, gained through their projects.

> **"One of the things I liked the most about the LSARP structure now (and it seemed like a pain back then) … I learned so much working with the social scientists, they taught me so much about social science, this is a huge benefit… but those relationships need care and nurturing."**
>
> *— Project Leader in the 2015 Large-Scale Applied Research Project Competition – Natural Resources and the Environment: Sector Challenges*

[8] Public science initiatives such as the one run by CIHR: http://www.cihr-irsc.gc.ca/e/documents/cafe_scientifique_evaluation_e.pdf

The figure below summarizes the findings related to the value of integrated GE³LS research in terms of ultimate outcomes, translational pathways, and intermediate outcomes.

**Figure 2: Value of Integrated GE³LS Research**



## B. The Vision of Integrated GE³LS Research

Since it was first introduced in 2000, GE³LS research has evolved through each competition; this has resulted in the term "GE³LS research" being interpreted differently over time. While it is normal for this type of fluid interpretation to emerge, it also runs the risk of losing a common understanding and vision amongst all researchers and other stakeholders.

### i. Reinterpreting the Term "GE³LS Research"

In the first two competitions considered under the Review (2008 and 2010), GE³LS was understood as the ethical, environmental, economic, legal and social "issues" or "aspects" related to genomics research. From 2012 onwards, it has been described more broadly as activities "undertaken from the perspective of the social sciences and humanities, but not limited to the disciplines that make up the acronym."[9]

Nevertheless, because the acronym GE³LS specifies five domains that are closely related to academic disciplines, confusion persists. For some researchers or stakeholders, the term remains limited to the disciplines that correspond to the acronym. Indeed, some Project Leaders commented that seeking GE³LS Leads from disciplines other than those covered by the current acronym is often discouraged.

For others, particularly new Project Leaders, it is often is initially unclear whether all topics listed in the acronym should be part of the GE³LS research plan. Others commented that there often is considerable pressure to focus on or to include economics research at the expense of addressing other important questions. In fact, there were very few funded projects that did not include economics research.

Regarding economics as a core research area, several peer reviewer survey respondents noted there is confusion between evaluating GE³LS research and evaluating whether an application demonstrates that the project deliverables have the potential to result in social and economic benefits (SEBs).[10] This confusion between GE³LS research and SEBs appears prevalent in health-related competitions where most projects have included economic research. This may arise from applicants trying to address an overarching objective of the RFA, namely having to demonstrate that their genomic-based applications could contribute to improving the cost-effectiveness of the healthcare system.

Another source of misunderstanding relates to whether GE³LS is exclusively a research endeavor, or whether it describes other activities. Some peer reviewer survey respondents, as well as some Research Oversight Committee members and users described GE³LS as a knowledge translation activity (e.g. communication, education and outreach, assisting

[9] Specific text of the RFA reads: "[GE3LS research] should be understood broadly as genomics-related research endeavors and related activities undertaken from the perspective of the social sciences and humanities. Therefore, it is not strictly limited to disciplines that make-up the acronym but rather encompasses all those that rely on quantitative and qualitative methodologies to investigate genomics in society, and help establish a basis to inform applications, practices and policies."

[10] See also Appendix Three: Peer Reviewer Survey Results.

in commercialization of products, supporting business interests, etc.) rather than as a research approach. GE³LS Leads with knowledge of the earliest competitions within the scope of the Review described a similar blurring between engaging in GE³LS research and "providing services."

Despite these various misunderstandings, a considerable majority of survey respondents, including most reviewers who self-identified as GE³LS reviewers, found that the term "GE³LS" remains acceptable even though it is clumsy or awkward. Amongst others interviewed for the Review, there is also a consensus that the term is well-known in the broad Canadian research community (i.e. among researchers, research administrators and other funders).

Therefore, the Expert Panel believes that the term GE³LS should be retained by Genome Canada and the Genome Centres but be explicitly understood as having a broader reach to include **research endeavors related to genomics across the life sciences, which investigate the implications these scientific and technological innovations have on society**. Herein this will be referred to as "research into the implications of genomics in society."

## ii. A New Definitional Framework of "Integrated" GE³LS Research

Descriptions of "integration" of GE³LS research also have evolved over time. For instance, in the 2015 RFA, the following explanation was provided:

> The overarching objective of integrated GE³LS research is to investigate the relevant factors affecting the advancement of the genomics research proposed and to support collaboration between genomic scientists and GE³LS researchers throughout all aspects of the research project (including research management and oversight). Integrated GE³LS research should be closely related to the overall project's objectives, deliverables and potential social and/or economic benefits. The scope should be more targeted than in large-scale GE³LS research, but the depth of the investigation must be sufficient to provide findings that can be applied to the project, as well as the broader sector. Moreover, the nature of the research outputs should have the potential to assist in the likely successful uptake of the project's deliverables.

To promote the broader interpretation of GE³LS research presented above and to further clarify expectations regarding "integration" of GE³LS research, the Expert Panel recommends the following framework:

> Integrated GE³LS research is a key instrument to study the implications of genomics in society which requires a team-based approach that is collaborative, integrative and applied, such that researchers with different disciplinary expertise, using a variety

of research strategies and methodologies contribute to a broader understanding of the scientific problem and the responsible and effective development and uptake of genomic-based solution(s). Such a team-based approach entails engagement between researchers contributing to advancing genomic science and researchers contributing to investigating the societal considerations.

This research component should investigate key societal factors that may facilitate or hinder the acceptance and uptake of the genomic-based application(s), such that it provides evidence that can inform and help implement changes in policy or practice related to the use of the genomic-based application(s). To achieve these complementary objectives, research questions should be developed with intended users as well as other decision-makers and/or policy-makers who can help identify barriers and define knowledge gaps that need to be addressed.

To broadly investigate the implications of genomics in society (including but not limited to those that focus on ethical, environmental, economic, legal or social issues), it is expected that GE$^3$LS research will be conducted by researchers from diverse disciplinary backgrounds, including but not limited to social or behavioural sciences, law or the humanities.

## Recommendation 2: Enhance Implementation of the Integrated GE$^3$LS Research Vision in Large-Scale Projects

Genome Canada should review its competition processes used to support funding of large-scale projects to address perceived or identified barriers to selecting strong integrated GE$^3$LS research. Program requirements, activities to assist team formation and research development, review criteria and processes, the selection of peer reviewers and members of Research Oversight Committees are amongst the key elements that must be aligned with the definitional framework suggested in Recommendation 1, particularly to reflect the diversity of research expertise involved in projects, and to account for the complexity of translating (genomics and GE$^3$LS) research results into tangible benefits.

The Expert Panel strongly encourages Genome Canada to take all appropriate actions at the earliest opportunity, starting with the 2018 LSARP competition, and to be completed over the next two competitions.

The Expert Panel's second recommendation primarily addresses the second key deliverable regarding indicators of success and factors that contribute to or inhibit successful integration. In developing this recommendation, the Expert Panel focused on Genome Canada's LSARP competition processes, guidelines and criteria to determine how they affect the development and selection of integrated GE$^3$LS research.

From the perspective of the Project Leaders and GE³LS Leads who were interviewed, two stages through the course of a competition appear to have importance in terms of the integrated GE³LS research: team formation and the development of the integrated GE³LS research plan and, once projects have been selected for funding, interactions within the team during the project. Genome Centres also consider team formation and research development to be a critical stage.

In addition, the Genome Centres along with Genome Canada recognize that the peer review process is also an important stage, since integrated GE³LS research is evaluated by international experts whose assessments become valuable guideposts.

Below, these three stages are considered in the order in which they occur through the course of a competition.

## A. Team Building and Development of Integrated GE³LS Research

Genome Centres indicated that helping build teams that include GE³LS researchers and assisting in the development of integrated GE³LS research plans is one of the most time-consuming aspects of a competition, which often begins prior to its launch and continues as teams advance from one review stage to the next. Genome Centre staff described that genomics researchers who have never collaborated with researchers that are not from the natural or biological sciences rely heavily on the Genome Centres' assistance to identify potential GE³LS research collaborators, which is one of the first steps once a competition is launched.

Project Leaders who had received advice from the Genome Centres regarding potential GE³LS Leads to include on their teams were struck that much emphasis was placed on including well-known, established GE³LS researchers, rather than finding an expert that "fits" the project.

Many Project Leaders described instances where, once the Genome Centre proposes a GE³LS Lead, it his or her expertise that determines the GE³LS research questions. They worried this approach may contribute to disjointed projects. However, they explained that it can be a heavy onus on them to determine GE³LS research questions critical to the scientific research and then find researchers with the relevant expertise and skills to execute it.

All Genome Centres noted that involving GE³LS researchers early in the planning stage of the project is most advantageous. In contrast, when a project comes forward with a well-developed scientific research plan, it is more difficult to add the GE³LS research, as a final component.

This is corroborated by Project Leaders and GE³LS Leads who described a collaborative process, where GE³LS research plans were shared with and refined by the Project Leaders, which they believed yielded stronger proposals. However, many GE³LS Leads described that the development of the GE³LS research started from a broad understanding of the genomics research to be undertaken and proposing research questions that they were best suited to undertake, without or with limited additional input from the Project Leader.

From the perspective of the GE³LS Leads, developing strong integrated GE³LS research plans can be further challenged when advice is provided by Project Leaders, other team members, or Genome Centre staff that is later contradicted by peer reviewers. Many GE³LS Leads referred to a difficult balance between developing a GE³LS research plan that can withstand the scrutiny of expert reviewers as well as meet the expectations of others who were not experts in GE³LS research-related disciplines.

Several Project Leaders noted that, with experience over competitions, they became more attentive to the GE³LS research component and the necessary expertise. Similarly, GE³LS Leads who had benefited from prior experience in large-scale standalone GE3LS research projects and/or other integrated GE³LS research activities explained they were better prepared to provide the expertise and develop integrated GE³LS research plans that would satisfy Project Leaders and meet the competition requirements.

## i. Success Factors in Building Teams and Developing Integrated GE³LS Research

When building project teams and developing research plans researchers identified the following key success factors for ensuring well integrated GE³LS research as part of their application for funding:

- **Identifying GE³LS researchers with the right expertise to address questions related to the project, rather than developing the research around the expertise of the GE³LS Leads.**
  Many Project Leaders indicated that it is preferable to first identify GE³LS research questions that are aligned with the genomics research and then find the right expertise. However, they also recognized that this requires some understanding of the nature of GE³LS research, something most Project Leaders did not have at the time of their first application for Genome Canada funding. They also acknowledged that finding the right expertise is challenging, as opportunities for genomics scientists to meet potential GE³LS collaborators are rare. Project Leaders who appeared to have greater ease in identifying relevant questions and finding the right expert often were from inter-disciplinary departments.

- **Pre-existing working relationships and/or familiarity with each others' work, which facilitates building trust and establishing strong working relationships early on.**
  In several case studies included in the Review, the collaboration between a Project Leader and a GE³LS Lead extended beyond a single project. All such pairs of researchers expressed the advantages of such continuity in terms of: greater mutual understanding between Project Leaders and GE³LS Leads; the GE³LS research proceeding with greater ease; and/or the GE³LS research being better focused in the subsequent project.

From these examples, it appears that when Project Leaders have formed a good collaboration with a GE³LS Lead, they rarely seek out new GE³LS research collaborators; in these case studies, there is only one instance where the Project Lead sought additional expertise to help address a different set of GE³LS research questions in a subsequent project.

Other case studies showed that, apart from collaborating on consecutive LSARPs, other pre-existing relationships also were beneficial, such as having been involved in other research collaborations or being university colleagues.

- **Early involvement of GE³LS researchers and team-based approach in developing the GE³LS research; avoiding GE³LS research that is merely "tacked on."**
  Multiple case studies showed that involving GE³LS Leads early in the process of preparing an application contributed to a more collaborative approach to developing the GE³LS research aims and activities. This prevents GE³LS research merely being "tacked on" to the overall project, and can also help align critical milestones whereby GE³LS research findings might affect genomic research activities, or vice versa. Additionally, there were cases where the early involvement of the GE³LS researchers contributed to early engagement of users.

- **Understanding users' needs and working back from these to help GE³LS research deliver results.** The early inclusion and on-going involvement of users also appears critical. Case studies illustrated that engagement of the users through the GE³LS research helped its development, leading the team to collect data in areas that were not previously considered, such as regional differences in industry practices. In one case study, the Project Leader reported that the eventual dissemination of research was also made easier through the early inclusion of the users.

## B. The Review Process

The Expert Panel examined two stages of peer review: the pre-application stage and the full application stages, to assess whether the review process and review criteria were factors that contribute to the successful integration of GE³LS research.

### 1. Pre-Application Review

**Stage 1**: The first stage is done "at home" by an International College of Reviewers who primarily evaluate the merit of the research plan and the potential for social and/or economic benefits for Canada.

**Stage 2**: In the second stage, the highest-rated pre-applications are reviewed by the Pre-Application Review Committee (PARC) whose members have

appropriate expertise to evaluate the merit of the research plan and the potential social and/or economic benefits for Canada. The PARC makes a recommendation to Genome Canada regarding the most competitive proposals to be invited to submit a full application.

**2. Full Application Review**

Applicant teams that are successful at the Pre-Application stage will be asked to submit a Full Application. These more detailed applications are assessed against all the evaluation criteria (i.e. research proposal, social and/or economic benefits, management and finance). The International Review Committee meets with and interviews representatives from each of the project teams that have submitted a Full Application through a reverse site visit mechanism. The recommendations of the Review Committee are provided to Genome Canada and, ultimately, the Board of Directors makes the final decisions with respect to funding.

The merit of the integrated GE³LS research component, as well as its degree of integration are assessed at each stage. The process to review the integrated GE³LS has changed over the years to determine the most appropriate mechanism. Currently, at the first stage of the pre-application review, a GE³LS expert is only assigned to review the project if the GE³LS research is a significant component of the overall project. At the second stage of the pre-application review, either a GE³LS expert or a reviewer with expertise in assessing the social and/or economic benefits is assigned to each proposal. At the full application review, each project is reviewed by at least one GE³LS expert.

During the Review, 85% of peer reviewers who responded to the survey believe there is an adequate review of the integrated GE³LS research through the in-person panel review process. Nevertheless, several concerns were raised related to the peer review process of the integrated GE³LS research.

- **Integrated GE³LS research may not always be assessed by reviewers with the appropriate expertise.** Reviewers did not always feel confident that they had the expertise to assess the full GE³LS research component of the project. The same concern was reiterated in interviews with Project Leaders, GE³LS Leads, and Genome Centre staff who noted that peer review panels often did not have the breadth of expertise required to assess the genomics and GE³LS research components equally or properly, and that there was much greater emphasis placed on the genomics research. The ability to ensure that integrated GE³LS research is reviewed by an individual with the appropriate expertise is complicated by the heterogeneity of the GE³LS research topics in a particular competition and the fact the GE³LS community is not large, increasing the chances that relevant experts may be in conflict.

- **The amount of transparency regarding the review process.** During the face-to-face meetings, in cases where no questions are asked about the GE³LS research, it is not clear to the applicants and the Genome Centres whether that portion of the application was reviewed, or whether no issue was identified regarding the proposed GE³LS research.

- **The level of clarity in instructions and guidance to reviewers and applicants.** In terms of review criteria, 82% of the respondents to the peer review survey agreed that the criteria related to GE³LS research supported the development and selection of good integrated GE³LS research. In contrast, many GE³LS Leads believed clearer explanations regarding the expectations for integrated GE³LS research and review criteria are needed.

- **The assessment of integrated GE³LS research through early stages, including "friendly reviews" performed by Genome Centres and the pre-application process, is insufficient/not rigorous enough.** In early stages, reviewers' ability to offer meaningful feedback is often hindered by the brevity of the GE³LS research proposal, which is embedded in the overall research plan and therefore limited by page restrictions.

Another topic that has received considerable discussion over the years is the process for rating the integrated GE³LS research, specifically:

1. Whether the integrated GE³LS research should continue to be rated as part of the overall research rating or be rated separately from the genomics research.

2. Whether there should be a minimum rating required for the GE³LS research, i.e., could a "weak" integrated GE³LS research component prevent a project from receiving a high enough rating to be fundable?).

Two-thirds of the peer review survey respondents believed there should be a separate score for the GE³LS research plan. When this topic was raised, interview participants did not believe a separate score would be beneficial. Reasons included:

- Given the breadth and depth of GE³LS research that is found across projects (i.e. some have a relatively modest scope of GE³LS research and others have an expansive scope), it would be difficult to rate GE³LS fairly. Specifically, large GE³LS research components that address a wide range of issues could be viewed more favorably and receive higher ratings (even though there is no explicit target as to the scope of GE³LS research that should be pursued).

- A separate rating would undermine the concept of integration.

- Projects are increasingly emphasizing translational research, where the separation of GE³LS from the genomics research is even more difficult.

- Peer reviewers did not always feel confident that they had the expertise to assess the full GE³LS research component.

There were also different viewpoints as to whether there should be a minimum rating required for the GE³LS research to fund a project. Genome Canada staff and Project Leaders emphasized that requiring a minimal GE³LS research rating to fund a project could result in projects with excellent genomics science not being funded due to "weak" GE³LS research, even if it were a small component of the proposal. Additionally, there were concerns that requiring a minimum rating would favor returning researchers since their teams typically would have become stronger over time.

GE³LS Leads who were interviewed were reluctant to see "weak" GE³LS research proceed as part of funded projects, but they also were concerned that integrated GE³LS research always risks being assessed severely, resulting in low ratings (in large part because research plans could never address all potential barriers and knowledge gaps). The Genome Centre interview participants noted that the concern of "weak" GE³LS research being pursued is currently alleviated as teams are given an opportunity to address perceived weaknesses in GE³LS research that are identified by peer reviewers and can be followed up and monitored through the research oversight process.

Overall, this evidence points to the need to review and continue to improve the peer review process to ensure it supports the integrated GE³LS research model.

## C. Conducting Integrated GE³LS Research

Once a project is funded and research underway, many factors can still affect whether the integrated GE³LS research will result in the desired outcomes as discussed above (See Recommendation 1: Affirm the Value and Vision of Integrated GE³LS Research).

Through the interviews with Project Leaders and GE³LS Leads, the following factors were highlighted:

- **Mutual respect**
  Some Project Leaders and GE³LS Leads referred to the long-standing divide between disciplines. Through mutual respect of each researcher`s expertise and curiosity in each other's disciplinary approach, the divide between genomics and GE³LS could be overcome.

- **Strong communication mechanisms**
  Ongoing and open communication is important to keep genomics and GE³LS researchers jointly informed of the progress of their respective research. This occurred via a range of mechanisms including phone calls or one-on-one meetings between the Project Leader and the GE³LS Lead, regularly-scheduled team meetings, interactions during Research Oversight Committee meetings, user group meetings or conferences attended by project team members.

  Even when there was good communication, however, GE³LS Leads described conducting their research such that it was conducted in parallel with the genomics research, rather than as fully "interconnected" or "interdependent" activities.

- **User involvement in the project**
  Some GE³LS Leads explained that engagement with potential users can help strengthen the integration of the GE³LS research throughout the lifecycle of the project by providing a bridge between the genomics research and the GE³LS research and helping the project address clear user needs.

Through the interviews with Project Leaders and GE³LS Leads, **valuable GE³LS guidance from the Research Oversight Committee** was also suggested as a possible factor of success. Research Oversight Committees[11] are established for each project with a mandate to provide advice and guidance to the research team to help ensure that the project achieves its stated objectives and milestones. They are constituted by, and report to, the Genome Centres.

Although there is no mandatory requirement to include a member with GE³LS expertise, in recent competitions, such expertise has been consistently included. However, it is worth noting that Genome Centres estimate that nearly half the individuals invited to participate on a Research Oversight Committee as a GE³LS expert initially claim they lack genomic expertise and may not be able to provide insights into the project. Interviews with the four Research Oversight Committee members indicate that many Research Oversight Committee members tend to be unfamiliar with GE³LS research initially and acquired a clearer understanding over time. Therefore, more clarity upfront regarding the purpose of integrated GE³LS research in large-scale projects would be beneficial to them.

Across the range of interview participants, there was general appreciation that Research Oversight Committees provide meaningful advice across all aspects of projects, including GE³LS research. However, the effectiveness of the Research Oversight Committee is generally predicated on the dynamic amongst its members. Some interview participants noted that feedback could be of mixed value and was not always as constructive or as useful as desired. For example, a GE³LS Lead described tension when the sole Research Oversight Committee member with GE³LS expertise disapproved of the use of a particular methodology, which had not been previously questioned by peer reviewers. Moreover, some were concerned that non-GE³LS experts often commented on the GE³LS research activities in ways that were uninformed and unhelpful.

Interview participants noted that having diverse disciplinary and sectoral perspectives on the Research Oversight Committee regarding the genomics research and its application helped provide strong overall guidance to the project and to the integrated GE³LS research through the duration of the project.

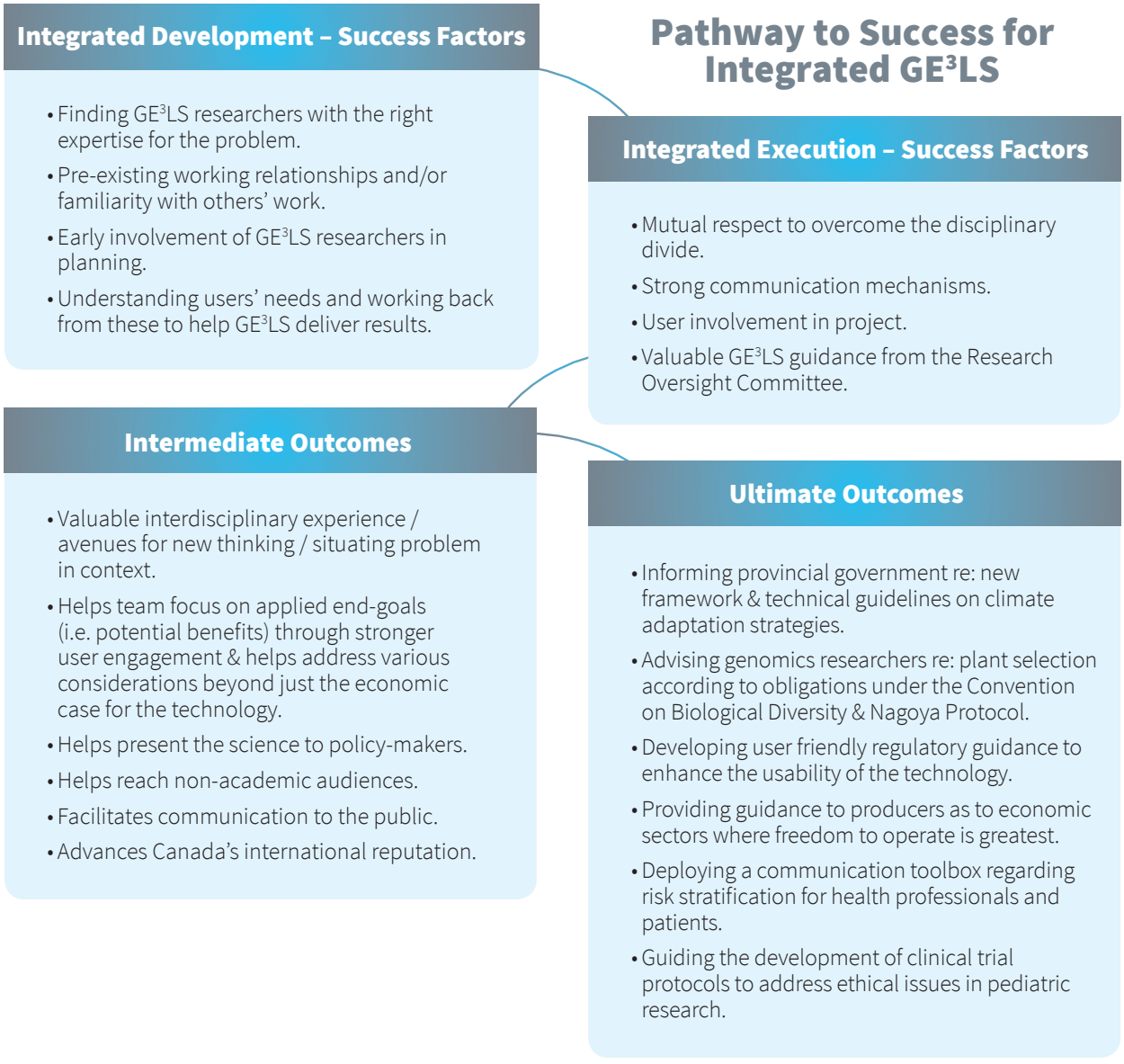
Some Research Oversight Committee members noted that GE³LS research often starts slowly, with few tangible outputs in the early stages of the project and, therefore, limited opportunity to offer advice. It may be late in the term of a project that genomics and GE³LS research can potentially inform each other. Specifically, one interview participant explained that when GE³LS research focuses on questions related to knowledge translation, it will provide little value until the end of the project.

[11] Research Oversight Committees were implemented in 2012; previously, projects received guidance from Scientific Advisory Boards, established by the project teams.

## D. An Overall Picture of Success

The Review has focused on the success of integrated GE³LS research in terms of intermediate and ultimate outcomes, whereby projects that were deemed "successful" often shared several characteristics in terms of their teams and their internal interactions, in addition to producing the ultimate outcomes that are expected of integrated GE³LS research, namely to facilitate translation and uptake. These findings are captured in Figure 3.

**Figure 3: Success Factors That Facilitate Translation and Create Valuable Outcomes**



Through this exercise, the Expert Panel found that integrated GE³LS research is a complex model. It therefore became necessary to consider factors that may bring about those characteristics, some of which are external to the project (e.g. peer review process) and which often rely on the support provided by Genome Centres and Genome Canada.

Without clarity about the expectations along the entire "lifecycle" of a project through the course of a competition, it is easy to see that integrated GE³LS research may be misunderstood or judged differently by various stakeholders. The Expert Panel, therefore, believes it is important that the LSARP program provide the necessary clarity and that there be support throughout the lifecycle of projects.

Clear instructions and expectations should be presented to genomics researchers from the outset of a competition being launched, so that their earliest interactions with Genome Centres can be based on a common understanding as they prepare their applications, build their teams and develop their research plans.

Clarity is also critical in the review process, particularly considering the diversity of expertise required and the reliance on international researchers, many of whom do not have any prior knowledge of GE³LS research. Similarly, members of Research Oversight Committees may be unfamiliar with this research model. The guidance they provide, therefore, may be timelier and more relevant if they acquire a good understanding of integrated GE³LS research from the very beginning of their mandate.

The Expert Panel recognizes that there have been ongoing efforts on the part of Genome Canada and Genome Centres to support the integration of GE³LS research in large-scale projects and believes these have paid off. Evidence collected for the Review pointed to a significant shift, from a time when many, perhaps most, researchers viewed the integration of GE³LS research as a perfunctory requirement to a growing recognition that it makes a meaningful contribution to projects. It encourages these efforts be further pursued in a comprehensive and concerted manner, along the entire span of the LSARP program, to help fulfill the vision of integrated GE³LS research described in this Report.

## Recommendation 3: Enhance Capacity to Conduct and Support Integrated GE³LS Research

To strengthen integrated GE³LS research, Genome Canada should undertake the following actions to increase capacity:

1. Build capacity to conduct GE³LS research as part of large-scale projects:

   Genome Canada should commit to increasing the breadth of researchers pursuing GE³LS research as part of large-scale projects, including early career researchers, including through the development of training opportunities.

Genome Canada should seek ways to enhance the collaborations with partners that support social sciences and humanities research and other interdisciplinary research, including universities, federal granting councils and other national or international stakeholders.

2. Build capacity to support GE³LS research leadership to enhance integration in large-scale projects:

   Genome Canada should reinstate a national senior position whose role would include long-term visioning and oversight of the GE³LS research program and, in the short term, supporting the timely execution of the recommendations set out in this Report.

   Genome Canada should provide targeted resources to support the Genome Centres' efforts to enhance integrated GE³LS research as part of large-scale projects. Where appropriate, Genome Canada should assist in the coordination of such work, or in the development of tools or other material that facilitates it.

Throughout the Review, the Expert Panel has emphasized that GE³LS research must be carried out by researchers who have the technical and methodological skills to conduct research on the implications of genomics in society; but it appears that only a small cohort of self-identified GE³LS researchers have participated in multiple projects and acquired extensive expertise. This is the challenge of capacity to **conduct** integrated GE³LS research.

The other challenge addressed by this recommendation relates to the various roles and responsibilities of the regional Genome Centres and Genome Canada throughout LSARP competitions. This is the challenge of capacity to **support** integrated GE³LS research, including to provide the leadership to develop the next generation of GE³LS researchers.

## A. Building Capacity to Conduct Integrated GE³LS Research

Much evidence considered by the Expert Panel pointed to the need for capacity building in the GE³LS research community.

- **The community of GE³LS researchers is small**
  It is understood that researchers who self-identify as GE³LS researchers (i.e. those who have participated in funded projects) comprise a small niche community. As a result, experienced GE³LS researchers are often involved in numerous applications, to the extent that it would be unfeasible to dedicate the number of hours stated in the application in every project if they all received funding. Another area for concern is that many of the established GE³LS researchers are approaching the end of their careers; to continue to primarily rely on them to support future competitions could be problematic.

- **Early career researchers face challenges**
  The GE³LS Leads noted that trainees are becoming interested in pursuing GE³LS research, as they recognize there is a paucity of research in many genomics-related areas, which presents great opportunities. However, early career researchers must overcome several challenges to become involved in Genome Canada funded projects. First, as early career researchers they may lack the required experience in contributing to complex large-scale research projects and may not be capable of leading integrated GE³LS research. Second, their ability to receive Genome Canada funding is challenged, as well-established GE³LS experts are, in fact, more likely to be funded. Genome Centres worry that international peer reviewers are less confident in more junior researchers (a concern also noted in relation to the genomics research component). In this regard, Genome Canada staff reported that reviewers often consider past funding successes, along with experience in managing large-scale projects. Third, Genome Centres reported that, due to time and resource constraints, they are challenged in balancing the recruitment of new or more junior researchers and engaging established GE³LS researchers.

- **The disciplinary divide**
  Interview respondents noted that disciplinary differences between the life sciences and the social and behavioural sciences, law and the humanities persist as they "speak different languages." Developing the ability to collaborate across disciplines requires significant support.

- **The breadth of Genome Canada's mandate**
  Some GE³LS Leads posited that researchers with relevant disciplinary expertise may be dissuaded from engaging in GE³LS research because of the applied focus of large-scale projects funded by Genome Canada. Additionally, GE³LS research expertise is unevenly spread across the sectors. This expertise-gap may be exacerbated in regional Genome Centres, which have been developing expertise

> "… [T]here are a lot of young and upcoming scientists and engineers who maybe because of their stature don't have the ability to pull off some of these things or may not be perceived to have the capability to pull it off, and we do need to take more risk. Funding individuals and see[ing] what they can do [through] small-scale, [low-]risk projects so they can build their career[s].
>
> My biggest concern is losing this capacity in our young folks to excel, and I want to make sure we don't have everything so outcome-based that we miss the next Einstein."
>
> *— User in the 2014 LSARP – Genomics and Feeding the Future*

in certain sectors and not others with the result that not all Genome Centres have access to all the GE³LS expertise they need. The Genome Centres' sectoral focus may be hindering the ability to identify all potential GE³LS researchers at a national level. This is further compounded by a growing demand for specific methodology and disciplinary expertise beyond ethics and law, to include economic analysis, diverse social science methods, regulatory science, implementation science and others. To overcome such challenges, some GE³LS Leads pointed to the value of facilitating interactions amongst the GE³LS research community, to spark more innovative research ideas, which could spread across sectors.

Interview participants were supportive of Genome Canada maintaining collaborations with the Canadian Institutes of Health Research (CIHR) to foster GE³LS research capacity in health. Although it was not discussed directly, the joint initiative between Genome Canada and SSHRC also helps develop additional research capacity and may be worth promoting more vigorously. Finally, some interview participants suggested Genome Canada may wish to explore whether the Natural Sciences and Engineering Research Council (NSERC) would collaborate in supporting social sciences research in the context of natural sciences research, as inter-disciplinary research has become more common in other programs supported by the federal granting councils (e.g. the Canada First Research Excellence Fund).

Identifying researchers with the skill sets and overall competencies to conduct integrated GE³LS research in the sectors that Genome Canada invests in and ensuring that a new generation of GE³LS researchers is prepared to lead integrated GE³LS research in future large-scale projects, therefore, represent a challenge but also an opportunity.

## B. Building Genomics Enterprise Capacity to Support Integrated GE³LS Research

The unique and highly effective Genomics Enterprise model calls for Genome Canada and the regional Genome Centres to work collaboratively in pursuit of agreed-to objectives in genomics research. One of the key roles of the Genome Centres is to assist applicants in preparing competitive applications, including building the project team, engaging with potential users and advising on the research strategy.

### i. Genome Centre Capacity to Support GE³LS Research

All Genome Centres have some capacity to support the development of GE³LS research, but all interview participants agree there is significant variability between Genome Centres in the degree and value of such support.

Project Leaders and GE³LS Leads generally agree that Genome Centres have provided increasing levels of support and advice in recent competitions. GE³LS Leads who received the most support generally interacted with the Genome Centres that have dedicated GE³LS staff – some Genome Centres self-identify as "small" and as "having fewer resources." Researchers who have participated in multiple competitions also noted variability over time due to staff changes.

The Genome Centres described undertaking considerable outreach activities (e.g. information sessions at universities) once the LSARP topic is confirmed, to share information and facilitate collaboration within the research community. However, mechanisms used by the Genome Centres to identify GE³LS researchers (e.g. contact management systems) quickly go out of date and need to be continually managed. They noted the absence of centralized tools that could be used by all six Genome Centres to facilitate this search (which, as described above, tends to be regionalized and/or to be focused on specific sectors).

Project Leaders and GE³LS Leads noted that most of the support occurs at the application stage (with some ongoing support through the lifecycle of the project, such as when issues are raised by the Research Oversight Committee). Project Leaders noted that Genome Centres helped with the preparation for the full application review by advising projects to make them more competitive as well as conducting reviews prior to applications being submitted to Genome Canada. However, a few GE³LS Leads noted that final preparations ahead of the face-to-face review were generally focused on the genomics research and that there was little feedback to improve the GE³LS research.

GE³LS Leads noted that much work can be done to help overcome the disciplinary divide between natural or biological scientists and researchers from the social or behavioural sciences, law and the humanities. They strongly believed that more events or workshops focusing on overcoming this gap would be valuable.

Genome Centres reported early engagement with users as another important element to ensure successful projects. Some Project Leaders noted that Genome Centres helped link them to appropriate users for their research.

The Expert Panel encourages Genome Centres to continue their efforts to support integrated GE³LS research and, when possible, to collaborate amongst themselves so that best practices become more evenly spread across regions.

## ii. Genome Canada Capacity: National Leadership for GE³LS

Since its inception in 2000, Genome Canada has been working to instill public confidence in genomics research and to overcome barriers to its application by fostering a deepened understanding of the implications of genomics in society. Through its Genomics in Society Program, Genome Canada invests in GE³LS research and supports outreach and communication activities.

The need for a leadership position at Genome Canada to help address GE³LS research issues that are national in scope, or to help support policy related activities was noted on several occasions by Genome Centre staff, as well as researchers. The former national director position was seen by GE³LS Leads as having been beneficial in helping build the necessary support structure for the GE³LS research community. The position has been vacant since early 2017.[12]

[12] History of leadership of program: 2000-2008 – VP National Genomics Programs; 2008-2010 – Chief GE3LS Officer; 2010-2014 – Director, National GE3LS Program; 2015-2017 – National Director, Genomics in Society

Many interview participants also explained, beyond guidance provided by Genome Centre staff, easily accessible material that provides diverse examples of GE$^3$LS research (particularly in sectors other than health) would be helpful, so that all researchers would have a better comprehension of the potential GE$^3$LS research that can be pursued. This would be particularly helpful with new researchers not familiar with GE$^3$LS research.

In summary, the Expert Panel urges that there be targeted actions across the Genomics Enterprise to secure Canada's continued leadership in GE$^3$LS research and the integrated model, including further efforts to expand the GE$^3$LS research community.

## Recommendation 4: Accountability for the Implementation of the Recommendations

Implementation and evaluation go hand in hand. The following actions are called for:

3. Recognizing the interest in this Review, the Expert Panel encourages Genome Canada to undertake a comprehensive consultation with the research community, Genome Centres and other stakeholders on the findings and recommendations of the Expert Panel. Following the consultation, the results should be shared with the Genome Canada Board through SIAC to help inform decision-making. In this way, Genome Canada would follow an accountability pathway for the implementation of this Expert Panel's recommendations.

4. Genome Canada should strive to assess the overall value of integrated GE$^3$LS research, its outcomes and its impact within Canada through the development and application of key performance indicators that capture the diversity of this research and its translational pathways. This should be part of an overall strategy for longitudinal performance evaluation.

The Expert Panel encourages Genome Canada to initiate these actions in partnership with Genome Centres, within 12 months of adopting these recommendations.

The Expert Panel's fourth recommendation focuses on accountability, in two regards. First, the Expert Panel believes the recommendations presented in this Report should be discussed by the wider stakeholder community. Also, Genome Canada should remain accountable to stakeholders by making transparent the final decisions it takes in relation to these recommendations. Secondly, the Expert Panel acknowledges the importance of demonstrating the value and impact of GE$^3$LS research and encourages the development of key performance indicators as part of the evaluation strategy for LSARP competitions.

## A. Stakeholder Consultation and Accountability in Decision-Making

One challenge the Expert Panel discussed is related to the limitations of an exercise such as the one that was undertaken to inform the Review. Although data were collected through multiple methodologies, including a set of case studies that spanned several competitions and sectors, additional points of view and opinions regarding the value and conduct of integrated GE$^3$LS research would help validate the findings detailed in this Report and the Expert Panel's recommendations, or help improve it, by identifying other gaps or weaknesses that were not addressed in the Review.

The Expert Panel therefore believes this Report would be more valuable if it were considered a first, albeit critical step, of a broader process. Next, Genome Canada should initiate a consultation with key stakeholders regarding the Report's findings and its recommendations. Such engagement with relevant stakeholders (including the Genome Centres, researchers and users) holds both symbolic and instrumental value.

Finally, the value of the Review will depend in large measure on future actions of Genome Canada. The Expert Panel believes transparency and accountability regarding decisions that are made, and their timely execution will be a key factor in ensuring Genome Canada's leadership in funding research that explores and helps address the implications of genomics in society. For these reasons, as appropriate, the Expert Panel specified timelines within which it would be reasonable for recommendations to be acted upon.

## B. Performance Indicators

This Report has provided examples of the value of integrated GE$^3$LS research and described success factors "that facilitate translation and create valuable outcomes." However, capturing the full diversity and complexity of integrated GE$^3$LS research activities and translational pathways throughout all funded large-scale genomics projects is an ambitious endeavor. Nevertheless, the Expert Panel believes that the ability to identify and quantify the impact and influence that emerge from LSARPs, and the contribution of the integrated GE$^3$LS research, is a critical activity to ensure that this research model continues to evolve to meet expectations of stakeholders, especially users of genomic-based applications, and in so doing serve the public interest.

Traditional academic performance indicators including publications, citations, number of trainees, may not capture the integrated GE$^3$LS research model well, nor may many of the

> "It's really good to have part of the thinking the impact the research could have. Sometimes you chase down an idea because it's a wonderful idea, it sounds so cool and sexy and then you don't know what the impact could be on society. It behoves the scientist, as a scientist, to think about how our research will impact society… the environment… our health… our economy."
>
> *— User in the 2014 LSARP – Genomics and Feeding the Future*

research indicators and outcome measures orientated toward commercialization, such as the number of spinoff companies, patents or IP development. Moreover, as was noted in many interviews, timelines for outcomes to be realized vary enormously between projects; therefore, these interview participants favored a longitudinal approach.

To understand fully the impact of integrated GE$^3$LS research, new indicators and methods for tracking project outcomes may be needed, with adequate support to ensure consistency and quality in reporting. This will help address several challenges in capturing outcome data for integrated GE$^3$LS research, which were identified through the Review and are presented below.

- **Outcomes often occur after the completion of the project where they are not tracked or monitored.**
  Most interview participants cited a 3- to 10-year timeframe, past the completion of the project, for observing significant outcomes and impact from the research. Project proposals are not always realistic in the outcomes that they anticipate by the end of the funding period. According to the Genome Canada interview participant, this situation appeared particularly acute in the 2012 LSARP competition, as many projects significantly underestimated the time required to realize outcomes in the healthcare sector.

> You need to have a stable level of funding…There is a huge emphasis by a lot of governments that you need results in two to three years… That doesn't necessarily happen… I think it really squashes a lot of innovations and stops people doing crazy things because [of] the push to produce. I believe in a bit of chaos and eureka moments, and you need people to be able to play around with stuff and go 'oh that's interesting.'
>
> *— User in the 2014 LSARP – Genomics and Feeding the Future*

  Monitoring of key performance indicators, that are SMART (specific, measurable, achievable, relevant and time-bound), and the evaluation of competition effectiveness should occur beyond the end of projects to track outcomes more fully, rather than relying on final reports, which mainly collect information related to outputs

- **Outcomes may be unanticipated or resulting from unplanned research opportunities and therefore are not always easy to track.**
  Some GE$^3$LS Leads noted that there often are research opportunities that are unanticipated at the time a project is developed. Yet, if pursued, those may yield the most interesting outcomes (e.g. a trade ban affecting crops being studied, which raised questions related to the economic impact), or may extend beyond the project term. Since these were not planned, they often are not tracked or reported.

- **Outcomes are diverse; intermediate ones generally occur during the project; ultimate ones generally become manifest only after the project has been terminated.**
  Although examples were provided of GE³LS research which led to the effective translation and uptake, other benefits were revealed. Therefore, different assessment methods and novel indicators may be required.

- **Outcomes may be commercially sensitive and cannot easily be tracked without compromising commercial advantage.**
  Interview participants noted that the challenge with tracking outcomes and impact of the commercialization of the research, especially if it is taken up by user companies involved with the project, is that a lot of the work is sensitive and confidential and therefore cannot easily be disclosed or attributed to the original research project

- **Outcomes may be counted/claimed by multiple partners such that it is difficult to determine the degree of attribution/contribution that is the result of Genome Canada's funding.**

The Expert Panel believes that Genome Canada should seek to fully capture the effectiveness of integrated GE³LS research in terms of outcomes and impact. Therefore, it should take the necessary steps to enhance the evaluation of funded projects; these findings should become an important source of information to continuously improve the LSARP competition.

# Conclusion

## Key Deliverables of the Integrated GE³LS Research Review

In addressing its mandate, the Expert Panel was to produce three key deliverables:

1. A definitional framework for integrated GE³LS research in Canada.

2. Key indicators of success; factors that contribute to the successful integration of GE³LS research; factors that may inhibit success; and strategies for removing these barriers.

3. An assessment of the effectiveness of integrated GE³LS research in contributing to the overall uptake of genomic-based applications.

Through the four recommendations presented in this Report the Expert Panel has addressed the deliverables, as follows:

## Deliverable 1: Definitional Framework

The Expert Panel first found that the research community and other stakeholders view Genome Canada as a leader regarding GE$^3$LS research and believe it should maintain this role and continue to support such research.

Additionally, despite persistent discussions regarding the acronym GE$^3$LS, the Expert Panel found strong reasons to recommend that it continue to be used to refer to this unique research approach. However, the Expert Panel also believes the term "GE$^3$LS research" should be interpreted broadly to include research endeavors related to genomics across the life sciences, which investigate the implications these scientific and technological innovations have on society (or, more simply, as "research into the implications of genomics in society").

Finally, integrated GE$^3$LS research is an approach that has evolved as part of large-scale, applied genomics research projects. **A definitional framework**, therefore, must account for the clear expectation that teams of researchers from diverse disciplinary backgrounds will collaborate to conduct applied research that potentially will result in genomic-based applications that can generate benefits.

Recommendation 1, therefore, presents a definitional framework of integrated GE$^3$LS research that builds on affirming the value and vision of research into the implications of genomics in society.

## Deliverable 2: Key Indicators of Success, Factors that Contribute to or Inhibit Successful Integration and Strategies to Remove Barriers

To identify indicators of success and factors that contribute to it, the Expert Panel considered the "lifecycle" of projects through LSARP competitions. In doing so, it learned how teams are created and research plans developed in preparing applications for funding, how the peer review process addresses integrated GE$^3$LS research and how the research is executed over the term of a project. This information helped identify key success factors that can lead to valuable outcomes (See Figures 2 and 3).

In line with these findings, Recommendation 2, on enhancing the implementation of the integrated GE$^3$LS research vision, calls for Genome Canada to review key elements of the competition to ensure they are aligned with the definitional framework described in Recommendation 1.

Another factor that looms large when assessing the success of integrated GE$^3$LS research is "capacity." The evidence suggests that expanding the cohort of researchers interested and well equipped to engage in integrated GE$^3$LS research will require targeted action.

Moreover, to the extent that researchers rely heavily on the guidance they are provided about the LSARP requirements and those regarding integrated GE$^3$LS research, it is important that such support be robust, and that Genome Canada and regional Genome Centres develop internal expertise, which can be coordinated and leveraged across the country to meet evolving needs.

Therefore, Recommendation 3 addresses capacity to conduct integrated GE³LS research as well as capacity to support it.

### Deliverable 3: An Assessment of the Effectiveness of Integrated GE³LS Research in Contributing to the Overall Uptake of Genomic-Based Applications

The Expert Panel found several examples where the integrated GE³LS research contributed to the uptake of the genomic-based application resulting from the project (See Recommendation 1: Affirm the Value and Vision of Integrated GE³LS Research); nevertheless, a systematic assessment of the contribution of integrated GE³LS research to the uptake of genomic-based applications was not completed and would prove challenging at this time. This is partly due to the lack of comprehensive metrics to assess the outcomes of projects and distinct metrics that could help assess the contribution of the integrated GE³LS research to this goal. Therefore, the Expert Panel believes greater efforts will be required to attain a better understanding of the full impact of integrated GE³LS research over time.

The final recommendation on accountability for the implementation of the recommendations extends beyond assessing the effectiveness of integrated GE³LS research by encouraging Genome Canada to be accountable to stakeholders regarding decisions that it will make in relation to all four recommendations presented in this Report.

## A Call for Other Funding Mechanisms for GE³LS Research

Although the Review focused on integrated GE³LS research funded as part of LSARP competitions, interview participants had the opportunity to discuss limitations of this model, as well as whether other funding mechanisms should be considered.

Many interview participants noted that by focusing on applied research questions within the parameters of specific genomic-based applications, the integrated GE³LS research model prevents the examination of more fundamental research questions, or questions of a broader scope, which were the object of large-scale standalone GE³LS projects in the early large-scale competitions (i.e. Competitions I, II and III).

Furthermore, in the context of sector-specific competitions, interview participants suggested it may be necessary to facilitate collaboration across projects when there appears to be overlap or duplication of GE³LS research questions, or to better address questions that are of a national scope, beyond a single project and its specific genome-based application. Genome Canada has recognized this desire to address broad sectoral issues and worked with the Genome Centres in 2012 to develop the translational network model, as an attempt to address key GE³LS research issues in personalized health in a national and strategic manner. Project Leaders supported the model, but some cautioned that this translational network was implemented too late and should have been initiated at the launch of the competition to have greater impact. Thus, Genome Canada should continue to support GE³LS research through the innovative translational network model but should improve upon it.

Additionally, Genome Centres have been considering new approaches to support GE$^3$LS research within their region and offered additional suggestions:

- **Pre-competition GE$^3$LS research funding**
  To investigate relevant issues prior to the launch of an RFA, to help inform the development of the science (either within projects, regionally, or nationally).

- **Post-competition GE$^3$LS research funding**
  To address translational and policy issues towards the end of projects and post-project;

- **User-driven research**
  To be carried out by users who may be engaged in research outside of academia, as they are more capable of translation and implementation; and

- **Regional programs**
  Similar to "translational networks," with a portion of the budget received by funded projects earmarked for a GE$^3$LS-related research project.

These various programmatic options could all contribute to developing capacity and gaining a broader and deeper understanding of the implications of genomics in society; therefore, the Expert Panel strongly encourages Genome Canada and regional Genome Centres to devote additional resources that will help support such initiatives.

The Expert Panel believes that diversity in funding structures can best ensure a more comprehensive understanding of the full range of implications of genomics in society. This could be carried out through large-scale standalone GE$^3$LS research projects, or by targeted competitions on cross-cutting sectoral barriers or knowledge gaps, which could be investigated by translational networks or through other forms of engagement with users or policy-makers.

GENOMICS IN SOCIETY
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