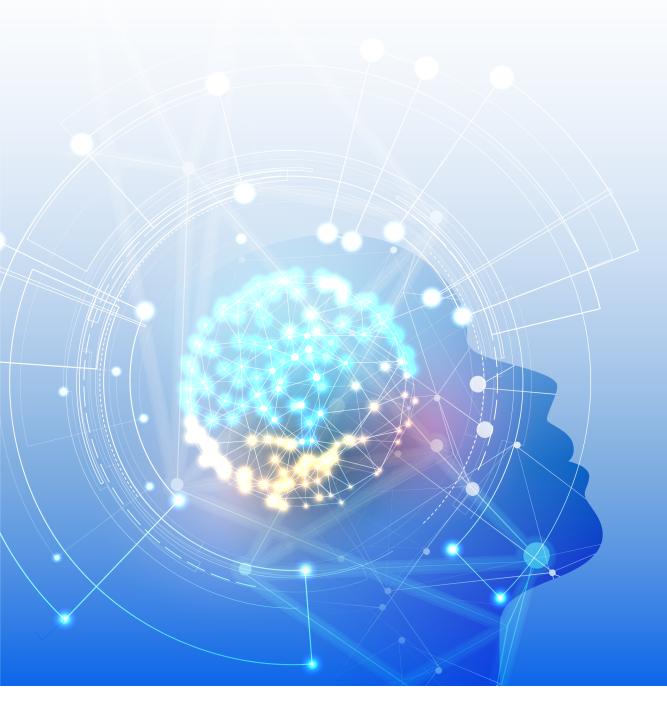
Health Canada **DATA STRATEGY**







Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health.

Health Canada is committed to improving the lives of all of Canada's people and to making this country's population among the healthiest in the world as measured by longevity, lifestyle and effective use of the public health care system.

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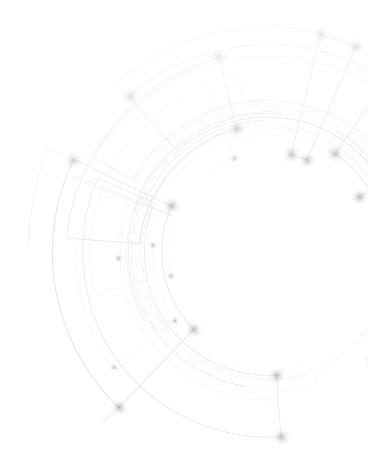
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Message from the Deputy Minister

I am pleased to provide Health Canada's Data Strategy, the first of its kind for our department. Completed in close collaboration with branches, this strategy reflects the increasing strategic value of data in providing insights to help Canadians maintain and improve their health, and how this value will be realized.

The need for a strategic approach to our data is imperative as greater digitalization of our operations and services is generating data of greater volume, variety and velocity. When governed and used appropriately, and at the right time, this data can be leveraged to inform our decisions. It is encouraging that so many branches have already started using their data as an asset and are undertaking bold initiatives of their own. This strategy strives to build on those successes and best practices from an enterprise perspective.

Health Canada generates and holds a vast, diverse and ever-expanding array of data, including program, regulatory, scientific and administrative data. Health Canada is also highly dependent on third-party data relationships to effectively deliver on its mandate. These include data relationships with other government departments, provinces and territories, environmental organizations, non-government organizations, community groups, academia, industry, others countries and jurisdictions, and international organizations. Managing our data, accessing partners' data and using modern analytical tools to gain insights is key to delivering on our mandate now and in the future.

With the vision of effectively using data as an asset to provide credible information, reliable advice and quality services, the Health Canada Data Strategy focuses on the following key areas:

- Communications: Health Canada has a foundational common understanding of data, collaborates with partners to access and reuse data and shares data with Canadians.
- People and Culture: Health Canada has the talent and capacity it needs to manage, use, and understand data.
- Governance: Health Canada has governance at the right levels to ensure that data is managed and leveraged as a strategic asset.
- Environment and Digital Infrastructure: Health Canada has the technology and infrastructure needed to turn data and analysis into action.

The overall outcome of these efforts is to unlock the value of data by sharing it with Canadians and using it to inform decisions, design programs and deliver services that are more effective.

We now need to focus on concrete actions to unlock and harness the value in the data we have, including through support of the DM Solutions Fund. The implementation of the data strategy will be tracked and communicated through established reporting mechanisms, including regular updates to senior management. You can expect the data strategy to be evergreen and evolve over time. A new role of Chief Data Officer for Health Canada will be created in the coming months. Stay tuned for more information.

I look forward to working with all Health Canada employees in advancing this important cornerstone of our work.

Stephen Lucas, Ph.D.

Deputy Minister

Executive Summary

In recognition of the strategic importance of data, in November 2018, the Clerk of the Privy Council shared the Data Strategy Roadmap for the Federal Public Service and asked all departments to develop a data strategy by September 2019. The Government of Canada Roadmap sets out a whole-of-government approach toward a more strategic use of data, including more value for Canadians from the data we hold. It underscores the Government of Canada's need to rapidly evolve to keep up with citizen expectations, current business models, and other jurisdictions when it comes to leveraging data as a strategic asset. The Roadmap contains 21 recommendations to be advanced by the Federal Public Service, the first and foremost being to establish a departmental data strategy by September 2019.

Corporate Services Branch (CSB), Business Renewal and Enterprise Architecture Directorate (BREAD), was given the mandate to develop a "bold" data strategy that would inform an enterprise vision for the strategic use of data. With the support of colleagues across the department and the wider Government of Canada data community, BREAD has developed this Health Canada Data Strategy and taken significant first steps toward building a data-driven culture as follows:

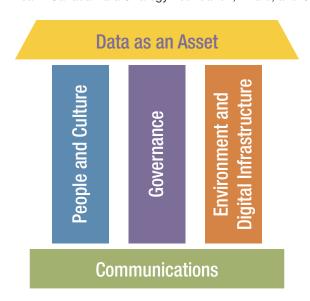
- A Data Strategy Executive Working Group with Assistant Deputy Minister appointed representatives from each branch was created to:
 - Provide strategic advice in acting as the governance for the strategy development;
 - Solicit data use cases from their branch stakeholders to inform the strategic framework and illustrate the 'art of the possible'; and
 - Co-design the strategic framework, in a workshop facilitated by Gartner Inc.

- An assessment of data maturity was conducted, providing a baseline against which Health Canada can monitor progress.
- An environmental scan of the department and across the Government of Canada was conducted to understand the current state and identify leading practices as it relates to data.
- Health Canada's first data Open House, and Data and Digital Day was delivered to departmental employees at all levels to build awareness, momentum and demonstrate data value.

Through the development of Health Canada's Data Strategy, we have the first departmental view of data. Health, regulatory and scientific data underpins effective and efficient delivery of all of Health Canada's programs. We hold and leverage significant amounts of data, have internal and external data partnerships, and have significant responsibilities to individuals and regulated parties whom share their data with us. From responding to national health crises to regulating health, consumer and commercial products and substances, Health Canada is committed to using data to make evidence-based decisions. Whether protecting the privacy of individuals or the confidential business information we receive from industry, the responsibilities are significant. Although some external data partnerships are in place, the opportunity is there to develop more of the relationships that will allow us to access and share timely and trusted data. This will require intentional efforts to design our data and data solutions to maximize value for our programs and for Canadians. While Health Canada is already making significant data investments, there is much more to do. The 2019 Health Canada maturity assessment found that data literacy and maturity levels have been increasing within pockets of the organization but not so much at the departmental ("enterprise") level. The current lack of governance on data at the enterprise level hinders the department's ability to collectively take stock of their data assets, identify intra-departmental linkages and opportunities for common digital data infrastructures.

Health Canada's Data Strategy responds to these findings and provides a strategic framework to realise the **departmental vision to effectively use data as an asset to provide credible information, reliable advice and quality services.** The strategic framework aligns with the Government of Canada Roadmap, while recognizing the diverse mandate of Health Canada—from fostering sustainable health care systems to promoting and protecting the health of Canadians.

FIGURE 1. Health Canada Data Strategy Foundation, Pillars, and Outcome



The following five principles have been established to guide the department toward the vision:

- Everyone is Responsible: Everyone is responsible to ensure data is of high quality and accessible to those who need it.
- Sharing and Reuse: Data is collected from users once, designed and managed for reuse and shared where appropriate.
- Maximize Value: Ensure data is designed to maximize usage and value, while incorporating privacy, security, confidentiality and ethics measures.
- Enterprise Tools and Training: Appropriate tools and training are available to manage and use data effectively, leveraging enterprise tools where possible.
- Leverage Governance and Stewardship: Data is a strategic asset that is architected and managed at the enterprise level through effective governance and stewardship.

The ultimate outcome is using data as an asset: unlocking the value of data by sharing with Canadians and using it to inform decisions, design programs and deliver more effective services. Specific goals (refer to Table 1) and actions (Table 2) toward achieving this outcome have also been set out.

The immediate next steps include launching the Data Strategy and developing the Health Canada Data Strategy Roadmap. These activities will be led by CSB, BREAD and include the following:

- Identify and assess governance roles and responsibilities, starting immediately with those of a Chief Data Officer, to determine which of the existing structures are best suited to provide oversight to data.
- Tap into departmental and CSPS learning services to promote available data literacy opportunities for employees.
- Identify early infrastructure partnership opportunities that programs might leverage.
- Build momentum and interest at all levels for establishing a data-driven culture through open houses and communications, including a launch event and data roadshow.
- Incorporate a data lens into the Enterprise Architecture review of investment planning projects, and continue developing a departmental Information Reference Model that will offer an at-a-glance view of departmental data, and be a starting point for data design.

- Accelerate concrete actions, including leveraging the DM Solutions Fund, to harness
 the value in the data we have, such as through data analytics to develop insights from
 existing data sets to support branch business needs.
- Increase public access to data and information.
- Work with branches and internal services providers to co-develop a multi-year Health Canada Data Strategy Roadmap to support implementation.

As is the case with the digital world we live in today, this document is intended to be evergreen, and allow for the department and branches to be agile and innovative in their approaches.



The Government of Canada Data Context

The Government of Canada has increasingly prioritized evidence-based decision-making and transparency. In the context of increased connectivity of people and devices, more data is now accessible to governments than ever before. The growth in volume of available data and the dramatic reduction in storage costs have changed business models and citizen interactions with government. These changes have the potential to augment decision-making and improve outcomes, services and government accountability to citizens. Ten years ago, the potential for individuals to mine extremely large and complex datasets for business or scientific insights was unimaginable. Given this new technological reality, departments must evolve to keep pace with rapid changes that demand new skills, tools, technologies and expertise to unlock the power of data.

The federal government is already taking measures to adapt to the digital age and effectively democratize data. To date, initiatives have included:

- the launch of the Canadian Digital Service to design and build simple and reliable technology;
- the modernization of Statistics Canada to increase access to data and to foster innovation and inclusion;
- the 4th National Action Plan on Open Government, which includes a commitment to improving transparency, accountability and public engagement; and
- the *Treasury Board of Canada Secretariat's Policy on Service and Digital*, which sets the foundation for the future of digital government in Canada.

In the context of these changes, the Clerk of the Privy Council issued direction to develop a Data Strategy Roadmap for the Government of Canada. The report, entitled A Data Strategy Roadmap for the Federal Public Service, was finalized in November 2018 and serves as a call to action to improve the way the Government of Canada collects, manages and governs data. Furthermore, the report establishes a foundation for how departments are expected to advance their own data agendas. The Roadmap contains 21 recommendations to be advanced, the first and foremost being to put in place a departmental data strategy by September 2019. Subsequently, it is important for Health Canada to:

- Provide greater clarity on who is in charge of data within individual organizations and for the government as a whole.
- Improve and develop overall standards and guidelines that govern how departments access, collect, use, safeguard and share data, and a clear process for developing and refining these over time.
- Clarify the governance around data to ensure that the Government of Canada manages valuable data assets for the public good.
- Improve recruitment and professional development practices to ensure that the department has the skilled people we need to do data work in a digital environment.
- Ensure the department has the right information technology (IT) environment that allows skilled professionals to use the disruptive technologies that will support the ambitious agenda outlined in this report.



Why Health Canada Needs a Data Strategy

The Value of a Data Culture

Health Canada generates and holds a vast, diverse and ever-expanding array of data, including program, regulatory, scientific and administrative data. Health Canada is also highly dependent on third-party data relationships to effectively deliver on its mandate. These include data relationships with other government departments, provinces and territories, environmental organizations, nongovernment organizations, community groups, academia, industry, other countries and jurisdictions, and international organizations. The Public Health Agency of Canada's Data Strategy is also highly dependant upon Health Canada's internal services for human resources, information management, information technology, and enterprise architecture.

Data has the power to enable Health Canada to make better decisions, design better programs and deliver services that are more effective. However, to do so, data should be fully understood, trusted, and carefully managed at the enterprise level like

EXAMPLES OF HEALTH CANADA DATA IN ACTION

Project Cyclops, a DM Solutions Fund initiative, involves the development of an app that would enable inspectors to use a smartphone or wearable device camera, to scan labels on health products. The technology, would verify the information on the labels and identify those that do not comply with Health Canada requirements. The technology would make the review process more efficient so inspectors can review labels instantly and invest more time into the inspection.

Under the Cannabis Tracking and Licensing System (CTLS), federal license holders, as well as provincially-authorized distributors and retailers are required to submit monthly reports to Health Canada. The Cannabis program's Business Intelligence Unit uses visualizations of this data to perform regulatory oversight, inform policymaking, and provide the Canadian public with key trends in the cannabis market.

any other departmental asset. Managing data is one thing, turning it into valuable insight is something else. It requires data literacy, or the ability to read, write and communicate data in context.¹ Data Analytics allows for the discovery of patterns and trends gleaned from data, and in turn information, to drive program decision-making and policy design.

Health Canada's Current Data Maturity

On the Gartner data maturity scale of level 0 "nascent" to level 5 "optimizing", Health Canada's 2019 maturity assessment was rated **as approaching level 2** "Developing" (Figure 2). The establishment of a Health Canada Data Strategy was an important factor in this maturity rating, as was the enterprise progress with investment planning governance, Enterprise Architecture, Government of Canada standards, privacy controls, and managing Access to Information and Privacy requests. There are also silos of specialised teams within the department performing complex analyses on the data that they hold or can access. However, from an enterprise perspective there is no single view of the departmental data priorities to support the valuation of our data and making strategic investments. The maturity assessment found that data literacy and maturity levels have been increasing within pockets of the organization but not so much at the departmental ("enterprise") level. The current lack of governance of data at the enterprise level hinders the department's ability to collectively take stock of their data assets, identify intradepartmental linkages, and opportunities for common digital infrastructures.

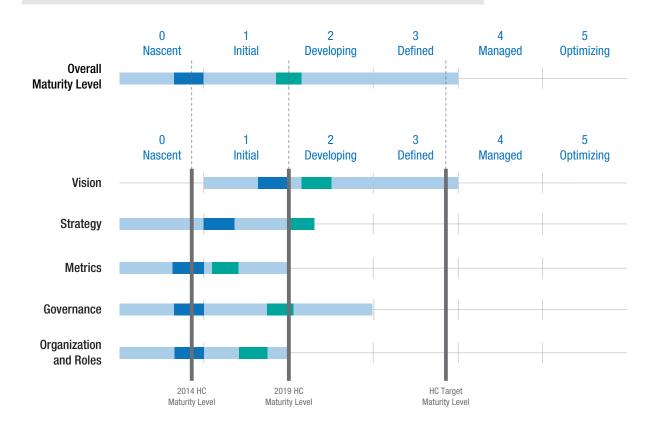
¹ Gartner, Fostering Data Literacy and Information as a Second Language: A Gartner Trend Insight Report, February 23, 2018



FIGURE 2. Health Canada Maturity Assessment

HC maturity level has moved from zero and is approaching **Level 2: Developing** due to the development of a data vision, strategy and goals; and increasing levels of data readiness and capacity in pockets throughout the organization.





Despite the data challenges, the pockets of progress are an encouraging sign of an organization heading in the right direction, and a good indicator of data readiness and capacity building. For example, there has been some progress as listed below:

- some branches have established data analytics teams, data science teams and a data analytics community of practice;
- progress on modernizing our systems, standardizing our enterprise architecture, and developing a regulatory reference model;
- increasing awareness of the importance of protecting personal information;
- continuing to release more data as an open resource, including digitally through Application Programming Interfaces (APIs);
- increased use of social media and web analytics data to improve outreach;
- early experimentation with artificial intelligence and machine learning to better leverage our data, improve services, business process automation and measuring effectiveness; and
- increased integration of performance indicators and reporting, including ensuring the quality of financial data.

These indicators point to an organization moving in the right direction in establishing a strategic approach to data, and poised for more rapid advancements in the near future. Strong governance of data will facilitate leveraging these advanced data maturity pockets and expanding best practices and lessons learned to the enterprise level. The Health Canada Data Strategy will support the transition to a digital data workplace and ensure employees are empowered and equipped to harness the power of data to make better decisions and create better outcomes for Canadians.

Existing Health CanadaData Priorities

Health Canada's programs fall under two core responsibilities: Health Care Systems and Health Protection and Promotion. Health Canada provides national leadership to support a health care system that offers appropriate and effective health care to Canadians. The department conducts research, analysis and policy work on health care systems issues and makes important investments to support several organizations that directly contribute to health system improvements. As a regulator, the department works with domestic and international partners to assess, manage and communicate the health and safety risks and benefits associated with health and consumer products, food, chemicals, pesticides, environmental factors, tobacco and vaping products, cannabis, and controlled substances.

Health, regulatory and scientific data underpins effective and efficient delivery of all of Health Canada's programs. From responding to national health crises to regulating health, consumer and commercial products and substances, Health Canada is committed to using data to make evidence-based decisions. Accessing data and leveraging it as a strategic asset requires collaboration with our partners, and the support of departmental internal service providers. As a scientific department, Health Canada has made significant data investments, as illustrated by the examples below.

Data in Health Systems

In its role as a funder, Health Canada is responsible for providing grants and contributions to a range of organizations in order to address government priorities, many of which relate to the collection of health data. Canada Health Infoway with the support of Health Canada funding, is working with provincial and territorial jurisdictions and other stakeholders to support the development and adoption of digital health technologies across Canada. Through this investment, Canadians will gain greater access to their own medical records and health care providers will be better able to coordinate patient care through digital technologies. In addition, with the support of Health Canada funding, the Canadian Institute for Health Information (CIHI) provides comparable and actionable data and information that is used to accelerate improvements in health care, health system performance and population health across Canada.

The Government of Canada's Data Strategy Roadmap calls upon departments to work with Indigenous partners, who are the custodians of their data, to co-develop indicators and data collection strategies. Health Canada needs data that represents Indigenous people in order to ensure well-informed health policies. Strategic Policy Branch's Office of Indigenous Affairs and Engagement (OIAE) was created to enhance responsiveness to Indigenous health relevant to Health Canada programs and policies. One of the key priority areas of OIAE is to increase the availability of research data, helping to build capacity in Indigenous health, and collaborating with Indigenous partners in ways that support reconciliation.

Health Canada launched a Sex and Gender Action Plan in May 2017 to systematically integrate sex and gender considerations into all Health Canada's research, legislation, policies, regulations, programs and services. The plan requires that all branches choose at least one key activity where they focus on the sex, gender and diversity aspects of the initiative. Through a Health Canada and Canadian Institutes of Health Research (CIHR) funding partnership, five research policy partnerships are in place to help ensure that departmental initiatives lead to sound science and reliable evidence which effectively addresses biological (sex) and sociocultural (gender and other identity factors) differences between different groups of women, men, girls, boys and or gender diverse people. At Health Canada, the Strategic Policy Branch will be leading the implementation of the Treasury Board's Policy Direction to Modernize the Government of Canada's Sex and Gender Information Practices. The collection of sex and/or gender data for sex and gender-based analysis purposes is encouraged as an integral part of evidence-based government policy- and decision-making. This initiative will help to ensure data accuracy, respect and inclusion of all groups of people, and the protection of individual privacy.

Data in Regulations

When the Government of Canada committed to the legalization and regulation of cannabis, Health Canada embraced the opportunity to design and implement a modern information management and information technology system for their licencing and regulatory inspection programs. The result: digitized processes that enable data analytics to inform risk assessments, inspection planning and to monitor program performance. The Controlled Substances and Cannabis Branch followed the lead of other regulatory branches (Pest Management Regulatory Agency, Healthy Environments and Consumer Safety) by launching a public-facing web portal to allow stakeholders to share electronic information with Health Canada in a quick and secure manner. Sharing Health Canada data with Canadians is also a key commitment in support of greater transparency and openness. Building on this success, the current Establishment Licensing and Inspection System investment project is the department's new direction in developing an enterprise solution for a common business space. This project addresses the current aging IT systems and paper-based processes to enable consistency of data management across multiple regulatory programs. The result of this investment will be high quality digital data for reporting, analytics, trending, monitoring, and risk management.

Health Canada's Deputy Minister launched the Solutions Fund in 2018, a Beyond 2020 initiative, that supports being agile in delivering results through employee-led innovation and experimentation projects. Solution Fund projects include experimenting with new data collection methods, as well as leveraging existing data to gain new insights through artificial intelligence. This funding is enabling the Healthy Environments and Consumer Safety Branch to conduct a proof of concept to test a systematic review approach for human health risk assessments using artificial intelligence. The Regulatory Operations and Enforcement Branch is also leveraging artificial intelligence and machine learning to gain new insights on data mined from regulatory inspection reports and databases, to inform risk-based decision making and program delivery.

Data in Science

In 2017 the Government of Canada established its first vision for science: strengthen science, strengthen evidence-based decision-making and strengthen the culture of curiosity in Canada. The Science-based Departments and Agencies (SBDAs) support the Government of Canada's Data Strategy Roadmap and its application. DG-Science at Health Canada is a forum for broadly based identification, analysis and discussion of horizontal science and risk-based issues to advance the department's policy and science priorities and objectives. This key science advisory body brings together the Health Portfolio partners (i.e. Health Canada, Public Health Agency of Canada, Canadian Institutes of Health Research and Canadian Food Inspection Agency). Health Canada's Science Policy Directorate (SPD) provides advocacy for science sectors across Health Canada including facilitating the following examples datasharing relationships:

- Several groups in Healthy Environments and Consumer Safety Branch have been actively
 using the Environment and Climate Change Canada (ECCC) / Shared Services Canada
 high-performance computing centre in order to access weather data and modeling tools.
- HPFB Food Directorate researchers, involved with the Genomics Research and
 Development Initiative Antimicrobial Resistance research project, are successfully
 employing a collaborative data platform at the Public Health Agency of Canada's
 National Microbiology Laboratory. This collaboration allows researchers to share and
 leverage genomics information with partner science-based departments and agencies.
- Health Canada scientific researchers in HECSB are leading projects to collect data for the Maternal-Infant Research on Environmental Chemicals research platform, which has the most comprehensive datasets on prenatal and postnatal exposure to multiple environmental chemicals.
- As a scientific funder, HECSB also supports the Northern Contaminants Program (NCP) that
 works to reduce and, wherever possible, eliminate contaminants in traditionally harvested
 foods for Indigenous populations. The NCP, in collaboration with their northern regional
 partners, plays a very important role in generating and sharing scientific information on
 contaminants in the Arctic, which assists informed decision-making by individuals and
 communities in their food use.

Data Environment and Digital Infrastructure

Health Canada's digital infrastructure, which includes its data, is critical to the department's ability to achieve its mandate, support and retain its workforce, and work more effectively with external stakeholders. One example are the recent investments made in upgrading the SAS Grid software, a key foundational data infrastructure for both Health Canada and the Public Health Agency of Canada (PHAC) to perform statistical analysis and advanced analytics. SAS is used by 520 epidemiologists, statisticians and data scientists, across ten Health Canada / PHAC branches, to analyze data from multiple sources in order to provide evidence-based results for national program delivery and policy decision-making.

Another example is that HECSB has rolled out several information management systems that have enabled them to discover and streamline common regulatory and business processes. Common data models have been developed and software deployed that enables over a thousand users to collect, share, work with, collaborate on, track, and report about the data they generate. The common data models have:

- generated new opportunities to collaborate with regulatory partners inside and outside Health Canada:
- enabled the branch to leverage advanced analytical algorithms and cutting-edge data visualization techniques; and
- driven the development of efficiencies in business processes.

Delivering on our Data Priorities

While Health Canada is already making significant data investments, there is much more to do from both the program delivery and internal service provider perspective. This Data Strategy commits to delivering a data culture, featuring a high degree of data literacy. Communicating about data, both internally and externally, will allow the department to build on successes and share best practices and lessons learned. Senior executive leadership is required to support a new data-driven culture. Leveraging governance at both the enterprise and branch level will be the starting point. In addition, internal service providers will need to understand the needs of branches and PHAC, working together collaboratively to create an enterprise environment and digital infrastructure.



Health Canada's Data Strategy Framework

Health Canada's Data Strategy Framework (Table 1) leverages the November 2018 Government of Canada Data Strategy Roadmap while adjusting its purpose based on Health Canada's mandate and priorities. Data communication supports three pillars to ensure Health Canada has the right people, culture, and governance, enabling environment and infrastructure to realise the outcome of treating data as a strategic asset and a source of insight.



 TABLE 1. Health Canada's Data Strategy Framework

VICION	Effectively use data as an asset	to provide credible information, relia	able advice and quality convices
VISION	Effectively use data as all asset	to provide credible illiornation, relia	wie advice and quality services.
GUIDING PRINCIPLES	Everyone is Responsible Everyone is responsible to ensure data is of high quality and accessible to those who need it. Sharing and Reuse Data is collected from users once, designed and managed for reuse and shared where appropriate. Maximize Value Ensure data is designed to maximize usage and value, while incorporating privacy, security, confidentiality and ethics measures. Enterprise Tools and Training Appropriate tools and training are available to manage and use data effectively, leveraging enterprise tools where possible. Leverage Governance and Stewardship Data is a strategic asset that is architected and managed at the enterprise level through effective governance and stewardship.		
OUTCOME	Data as an Asset		
	Unlock the value of data by sharing with Canadians and using it to inform decisions, design programs and deliver services that are more effective.		
PILLARS and GOALS	People and Culture	Governance	Environment and Digital Infrastructure
	 Health Canada has the talent and capacity needed to manage, interpret, use and understand data. Health Canada has an agile collaborative space for learning and innovative uses for data. 	 Health Canada has governance to ensure effective use of data at the enterprise level. Data is managed and used ethically while respecting laws governing privacy and security. Enterprise data management and stewardship is in place to enable data to be used as a strategic asset. 	 Make strategic investments in modern technology to create digital data and leverage it as an asset. Identify opportunities for digital data standardization, consolidation and integration.
FOUNDATION	Communications		
	sharing of Health Canada dat	ta needs, priorities and accessibilit a. and data collaboration with partne	-

Outcome: Data as an Asset

WHAT IS THE DATA STRATEGY TRYING TO ACHIEVE?

As stated in the Government of Canada Data Strategy Roadmap, data has the power to enable the government to make better decisions, design better programs, and deliver more effective services. By advancing efforts across our data strategy pillars and foundation, Health Canada is striving to achieve its vision to: **Effectively use data as an asset to provide credible information, reliable advice and quality services.**

WHAT WILL THIS LOOK LIKE?

With a strong analytics capability, the right skills and tools, and by enabling governance, Health Canada can begin to leverage data and more advanced analytics technologies and techniques—including artificial intelligence, predictive analytics, text analytics and deep learning—to inform its decision-making, scientific efforts, policies, regulations and services.

By bringing data from multiple sources together, and having the right tools and environments, Health Canada can enhance the rigor of analysis of program administrative data and increase the generation of new data to assess policy and regulatory outcomes, and strengthen performance measurement, program evaluation and policy development.

As a data-rich science-based department, Health Canada has an opportunity to deploy data and analytics across the organization to address key priorities. With quality data and strong analytics capability, Health Canada could start leveraging a combination of data sources to get a view of, for example:

- A geographic snapshot of Canadians who are ill, enumerated by therapeutic indications.
- A safety and efficacy profile of licensed medications in comparison to expected outcomes.
- Measuring the effectiveness of risk communications.
- Comparison of operational performance across the department.
- More timely indications of safety issues.
- Measuring and monitoring of risks to Canadians to access medications and health products.

In order to achieve these outcomes, the department must first establish a supporting structure in an incremental stepwise fashion:

- The highest priority and most valuable departmental data is identified.
- Data platforms and processes are in place to enable leveraging data as an asset.
- Compelling data visualizations inform program policies, design and decision-making.
- Employees feel empowered to use and make data available to others.
- Data use is appropriate, citizen- and business-centric, and ethical.
- Data is well managed, secure, and fit for use.
- Data can be integrated with data from other sources to create value for Canadians.

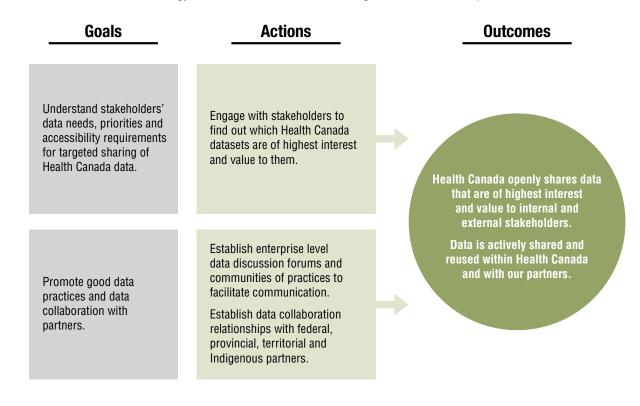
This will lead to the outcome of: Unlocking the value of data by sharing with Canadians and using it to inform decisions, design programs and deliver more effective services.



Foundation: Communications

WHAT WILL THIS LOOK LIKE?

FIGURE 3. Health Data Strategy Framework - Communications: goals, actions and expected outcomes



WHY IT MATTERS

It is critical that data sharing, access, and collaboration be encouraged across governments, with partners and Canadians, as indicated in the Government of Canada Data Strategy Roadmap. For far too long there has been an organizational culture of siloed singlepurpose data. To provide services and information that are useful to clients and Canadians, organizations must be aware of who their clients are, as well as their needs. By identifying types of users of data, we can better target our data products to the right clients and create better products with the client in mind. Data transparency and public access is important to increase confidence in government decision-making. The October 2014 Treasury Board of Canada Secretariat's Directive on Open Government requires all government data (structured and unstructured) to be open to the public by default unless subject to restrictions. The July 2016 Treasury Board of Canada Secretariat's Policy on Results requires departments to make available transparent, clear and useful information on the results a department is achieving. The November 2018 Government of Canada Data Strategy Roadmap highlights the need to take a user-friendly approach to data access. The Treasury Board of Canada Secretariat's Digital Operations Strategic Plan highlights the importance of understanding user needs in order to adopt a service-oriented, user-centred approach that puts stakeholder needs first.

The Government of Canada's Data Strategy Roadmap calls departments to recognize that Indigenous Peoples have an inherent right to self-determination, and to co-develop with Indigenous partners distinctions-based strategies to advance Indigenous data governance and institutional capacity. Health Canada needs to work with Indigenous partners, who are the custodians of their data, to co-develop indicators and data collection strategies. For example, the British Columbia First Nations communities have a Data Governance Initiative, which features a comprehensive and integrated approach to addressing complicated and long-standing socio-economic and cultural issues. The Initiative serves to unite and guide all BC First Nations, First Nations organizations and governments towards their shared outcome: well-being for First Nations.



OPPORTUNITY

Health Canada is the steward of a large amount of data, of which only a portion is made available to the public. The department needs to remain a trusted authority on health, science, and regulatory data through Open Data and by allowing Canadians and researchers to benefit from that data. By clearly understanding data client needs (e.g., what data they are using, how they are using it), Health Canada can better tailor its data services to support clients' needs, and ensure that datasets of the highest value to external stakeholders are prioritized for release on Open Data.

As the Government of Canada continues to embark on a journey to digital government, data is becoming a key driver and enabler on that journey. Most Government of Canada departments are actively trying to increase their data maturity, and find ways to improve the data culture at their departments as part of the transformation of programs and services to meet the needs of an increasingly digital clientele. As such, the opportunity strongly exists to share practices and data with other departments. Whether it is through great examples of data successes, collaboration on shared data problems, or creating space to experiment with data, the environment is certainly in place to take a collective step forward.

Pillar: People and Culture

WHAT WILL THIS LOOK LIKE?

FIGURE 4. Health Data Strategy Framework - People and Culture: goals, actions and expected outcomes

Goals **Actions Outcomes** Engage department on the data talent and capacity needs and Health Canada has assess the current state of data the talent and capacity literacy and competencies. needed to manage, Establish data talent interpret, use and development plans and understand data. **Employees and executives** recruitment strategies recognize the value of data and to address talent gaps. have the data skillsets to leverage data as a strategic asset. Health Canada has a culture where agile experimentation with data is Leverage Health Canada's encouraged and supported. DM Solutions Fund for data Health Canada has experimentation projects. an agile collaborative space for learning Promote data awareness and innovative uses across the department, for data. showcasing Government of Canada data stories.

WHY IT MATTERS

As a Government of Canada, we have embarked on a journey to a digital government. The Chief Information Officer of Canada has been elevated to a Deputy Minister position. Strong relationships and networks are being built with digital leaders domestically and internationally. Ever-increasing amounts of data is being generated and combined with new technologies and analytic methods to offer new opportunities to discover and develop new insights. This is creating a demand for staff who can collect, extract, mine, analyze complex datasets, and then present the findings in a manner to support decision-making. This requires a digitally data-oriented workforce. By focusing on data literacy and improving the availability and timeliness of data for decision-making, we enable better use of our data for improving operational efficiencies, policy research and program monitoring and evaluation. In order for Health Canada to actively contribute to the digital opportunity, we need to ensure that employees have the space to collaborate and identify innovative uses for data. Part of this is certainly strengthening the data culture and having the required skillsets, but it also requires the time and space to seek out new opportunities. This means bringing talent and data together with an openness to experimentation, learning from failures, and encouraging non-traditional data partnerships where appropriate.

OPPORTUNITY

As a science-based department, Health Canada has a strong culture of using data to make evidence-based decisions. Health Canada must retain this valuable and diverse expertise and talent while simultaneously attracting new talent to grow capacity and fill gaps. New public servants grew up in the digital era and bring to the workforce innate digital skills and knowledge. We need to refresh our approach to attract data talent and enable them with modern IT tools for complex data analytics. Improving our data literacy will also increase cooperation and trust between data partners, and help ensure that data ethics is a concept that is well understood and considered as decisions on data usage are taken. There is no "one fit for all" approach for maturing data literacy, but from an enterprise perspective, we can remove barriers to enable progress.

Increasing our data literacy and data analytics capacity, supported by formalising data competencies, will enable us to leverage our large holdings of structured and unstructured data of various types. As a data-rich department, Health Canada has an enormous opportunity to deploy data and analytics across the organization to address key priorities. Both professional development and smart recruitment to address the skills gap will be critical to achieving this goal.

In a time that is increasingly characterized by data, digital, new workplace designs, flatter work cultures, and multiple generations working together, it is critical to examine and adopt the mindsets and behaviours that will meet the changing expectations of Canadians. The desired outcome of Beyond 2020 is a Public Service that is more agile, more inclusive, and better equipped.



Pillar: Governance

WHAT WILL THIS LOOK LIKE?

FIGURE 5. Health Data Strategy Framework—Governance: goals, actions and expected outcomes

Actions Goals **Outcomes** Leverage governance to ensure the required level of data oversight, clearly defining data roles and responsibilities and designated accountabilities for Health Canada has decision-making around data. governance to ensure effective use of data Identify key data initiatives to at the enterprise level. bring to governance, learning and adapting the governance process for data by applying lessons learned and best practices. **Governance processes** are in place to ensure that the right people can make decisions around data promptly, confidently, Integrate privacy, security and transparently. and ethics considerations into the design and **Health Canada has the trust** Data is managed governance of data. of Canadians, clients and employees and used ethically to hold and use their data. while respecting laws Leverage frameworks governing privacy and standards for data Health Canada has high quality trusted and security. privacy, ethics and security data that can be confidently used leveraging the government and shared with Canadians wide communities. and partners. Enterprise data Develop and implement a management and stewardship is in place Health Canada Information to enable data to be used Reference Model. as a strategic asset.

WHY IT MATTERS

The Government of Canada's Data Strategy Roadmap calls upon departments to provide greater clarity on who is in charge of data within individual organizations and clarify the governance around data. Like many organizational assets, data is a shared responsibility. The November 2018 Government of Canada Data Strategy Roadmap assigns data management responsibilities to all employees of a department. However, success requires collaboration and participation from distinct leadership roles given that data is the foundation of digital government.

Organizations require a data leader to ensure that the enterprise is developing the data, digital assets and capabilities required to provide digital services. A data leader would be accountable for increasing the value of organization's data assets, building data capacity, and increasing data literacy. These are foundational to a strategic approach to digital service. A data leader would also take a broader view, integrating data into the development of the enterprise digital business strategy and roadmap and, ensuring its alignment with the enterprise architecture and branch business strategies. This formal data leader role would be new to Health Canada.

The Government of Canada Data Strategy Roadmap suggests a Chief Data Officer would take on the role of data leader. The roadmap specifically indicates that "...all organizations must clearly identify who is responsible for fulfilling data functions and it would be expected that most will choose to have a CDO to achieve the appropriate balance between data management (CIO) and privacy, governance and analytics (CDO)".

The CDO and the CIO should work in partnership, with clearly delineated roles, to ensure the strategic use and management of data, and to serve the business needs of the organization. The CDO would be responsible for leading the strategy, governance, data literacy, operational intelligence, and data analytics and science efforts, with a view to enable programs to ensure they are well positioned to leverage their data for insights.

More broadly, the CDO would generally take on the enterprise-wide responsibilities over the following:

- defining and maintaining the data strategy, and regularly assessing and reporting on the effectiveness of the data strategy in achieving the outcome of using data as an asset;
- championing that adequate data governance, accountability structures and processes are in place, while developing policies for quality, standards, integration, access and discoverability;
- providing leadership for data literacy, developing a robust data culture, data science and data analytics efforts, as well as experimentation on uses for data;
- promoting that data is designed to maximize value for the enterprise, and that solutions
 and services are designed to maximize the value of data, which includes providing a
 supportive role to the CIO in the identification of infrastructure.

The CIO role is a more established role. The CIO is responsible to identify, implement and optimize information management and information technology (IM/IT) solutions. Similar to the CDO, the CIO is also an enabler for the business lines by ensuring they have access to key data and digital infrastructure to deliver on their priorities. In the data specific context, the CIO would be responsible for leading operational execution in the form of data management. The CIO is accountable for ensuring modern technology and tools are in place to support the evolving digital needs of Health Canada programs and employees. The CIO is also responsible for optimizing technology through standardization and effective adoption while ensuring open government requirements are integrated in any plans for information applications, systems, or solutions.

Program areas need to play a key role as data holders and stewards. They are responsible for identifying their core business priorities and the data that supports those priorities. They are the leaders in data collection and analysis, and need to optimize the value of data analysis to use it for decision-making. They also hold responsibilities around data by participating in governance of data and defining data quality and standards, guiding and monitoring data quality within their domain, generating and consuming data for analytics and decision-making, and identifying and cataloguing datasets to be published. Business lines are also responsible for data dissemination, archiving and disposition (record-keeping functions).

Individuals will also be expected to be good stewards of the data they hold, including actively seeking ways to increase the use and value of their data. In a more data mature state, business lines may rely less on the Chief Data Officer for data activities and have greater accountabilities and responsibilities that are carried out internally, while overseen by established governance.

In addition to clearly defined data roles, organizations must leverage governance, to provide overall direction and guidance on the availability, usability, integrity and security of data. Governance is critical to enable data sharing, facilitate data lifecycle management, clarify accountability for data, and support informed decision-making, as highlighted in the Government of Canada Data Strategy Roadmap (2018) and the Treasury Board of Canada Secretariat's Policy on Service and Digital (2019). A sound governance program includes clear guidance for data stakeholders (standards, policies, processes, good practices, communications, etc.) in addition to decision-making bodies and roles. Leading approaches to governance include using an adaptive governance model—one that enables data holders and stewards with a governance style that suits the context of the business scenario and risk—and having a governance council, or a body which works to ensure that data and information support business initiatives.

Governance is also important to balance the strategic use of data with the protection of Canadians' personal information, rights and privacy. The same holds true for the protection of confidential business information that is often included in the regulatory submissions that industry and other regulated parties are required to provide to programs. In the same way that the personal information of individuals needs to be protected, so must the confidential business information of our regulated parties. Getting privacy and ethics right will actually enable increased use and sharing of data, since data stewards will have knowledge of the data limits and have confidence that they can use and share data without harm. Currently, there is a range of federal government reviews underway to safeguard data and privacy and support trust in government as a data steward. These include reviews of the Privacy Act, the Personal Information Protection and Electronic Documents Act and the Statistics Act. Integrating Health Canada's Privacy Management Division in governance of data will support compliance with applicable privacy legislation and policies, while establishing departmental best practices. The Government of Canada has recently released a National Cyber Security Strategy, outlining the key elements of the global cyber security environment. At Health Canada, cyber security of data assets is a shared partnership between information management, information technology, security service providers, partners in Shared Services Canada, and branch data stewards.

Data needs to be designed and managed throughout its lifecycle, from creation to destruction, and as such is a key practice to ensure that data is managed as a strategic asset to support government operations, service delivery, analysis and decision-making. As stated in the Government of Canada Data Strategy Roadmap, "Moving forward, government organizations will be significantly more data-enabled and data management will become just as important as human resources or financial management." There are indications that future funding requests will require demonstration of data management plans aligned to the FAIR principles (findable, accessible, interoperable, and reusable). Data cataloguing will facilitate finding data across the enterprise and making it accessible for reuse. Adopting data standards across the enterprise facilitates the ease at which data can be shared and reused. Together these principles will increase the value of the data we hold.

In particular, science-based departments and agencies (SBDAs) have collectively identified the need for a common strategic approach to science data management and for stronger horizontal collaboration in modernization efforts. Management of science data should be guided by recognized principles with the intent of implementing an advanced and forward-looking approach. Governance should exist to ensure that data is designed and managed holistically and ethically as a strategic asset.



OPPORTUNITY

Departmental programs benefit from governance because it ensures data is consistent and trustworthy. This is critical as more programs rely on data to make business decisions, optimize operations, create new programs and services, and improve sustainability. Effective governance of data permits an organization to understand its data assets, their quality, and location, and who is accountable for the data. It ensures that the departmental and accountability structures are clearly defined for the management of data. A critical enabler of governance of data is the network of data stewards who are mandated with the authority to ensure established data standards are respected. They are essential partners of governance, setting enterprise-wide data standards to ensure data is consistent and trustworthy, which allows for data integration across programs.

As the Government of Canada will be providing frameworks to help guide all departments in the areas of data ethics and data security, there is significant opportunity to leverage this work, maintain the momentum it provides, and adjust or expand as needed to meet the particular needs of Health Canada. These frameworks can help form the basis of guidance that data stewards across the department can leverage as part of their responsibilities. The greatest opportunity in regard to privacy, security, and ethics is to design our data and systems with these things in mind, as proactively including them in a new system or process is much better than reactively having to make changes. As one of many federal regulators, we are not alone in our responsibilities concerning the confidential business information that we receive from regulated parties. Together with other regulatory departments, we can ensure that best practices around confidential business information are shared and adopted by our programs.

High-quality data is essential for data analytics and business intelligence, as well as better operational efficiency. Data management frameworks allow departmental governance, data owners and stewards to confidently ensure high quality data is available for analysis, sharing and interoperability across the enterprise. The joint efforts of Science-based Departments and Agencies in managing science data will allow for a consistent approach to creating, collaborating, reusing and sharing data to spur exploration and discovery, innovation, social and economic growth. This practice will emphasize the value of data while encouraging a common strategic approach to its management.

Pillar: Environment and Digital Infrastructure

WHAT WILL THIS LOOK LIKE?

FIGURE 6. Health Data Strategy Framework—Environment and Digital Infrastructure: goals, actions and expected outcomes

Goals **Actions Outcomes** Engage Health Canada branches to assess their unique digital and data Make strategic infrastructure needs and investments in modern assess the current gaps **Health Canada has** technology to create and opportunities. digital data and leverage an environment and digital Establish a common set infrastructure that enables it as an asset. of enterprise data needs and facilitates data and supporting enterprise management and analytics. data tools. Data is collected on digital platforms that are designed with an enterprise view to facilitate consistency and reusability across the department. Identify opportunities Continue to leverage for digital data and integrate enterprise standardization, architecture into the design consolidation of digital data systems. and integration.

WHY IT MATTERS

The Government of Canada Data Strategy Roadmap highlights that in all departments there is an increasing need for tools to collect, store, analyze, manage, share, and visualize data. Enabling open standards, open source, interoperability, and the sharing of expertise requires access to a common set of data tools commensurate with common data needs. At the same time, departments need a flexible framework to explore new tools and more advanced options that are both interoperable and secure. The quality of our data and supporting infrastructure profoundly affects our efficiency and the experiences of our staff, as well as partners, stakeholders and citizens engaging with us through our data and digital services.

The Policy on Service and Digital focuses on the client, ensuring proactive consideration at the design stage of key requirements of these functions in the development of operations and services. It establishes an enterprise-wide, integrated approach to governance, planning and management. Overall, the Policy on Service and Digital advances the delivery of services and the effectiveness of government operations through the strategic management of government information and data and leveraging of information technology. The management of these functions is guided by a commitment to the guiding principles and best practices of the Government of Canada Digital Standards: design with users; iterate and improve frequently; work in the open by default; use open standards and solutions; address security and privacy risks; build in accessibility from the start; empower staff to deliver better services; be good data stewards; design ethical services; and collaborate widely.

The Treasury Board of Canada Secretariat (TBS) *Digital Operations Strategic Plan 2018–2022* highlights the continued need to renew or transition aging and mission-critical IT infrastructure in order to maintain access to quality information and data. Across the Government of Canada, digital strategic initiatives are exploring Open-By-Default and Tell-Us-Once approaches to leveraging innovative solutions, emerging technologies, common services, digital identity or digital by design implementations. Advances in machine learning and artificial intelligence are increasingly enabling the application of these potentially transformative new technologies to provide services faster, better and more efficiently. This combination of data and new technologies can enable new service approaches and levels of customization and personalization of services not previously possible.

The ability to extract value from our data and previously unused data sources requires new architectures, technologies, methodologies and tools in order to leverage successfully. To assist with the complexity of linking our program data and facilitating more collaboration and reuse, data architectures will need to be developed. These data architectures will facilitate a better understanding of how individual components of the system interact and how information flows, as well as the development of common naming conventions. Some of this work, and the associated investments, will need to be coordinated with our partners and based on common and agreed data standards, for accessibility, interoperability, quality, architecture and taxonomies.

OPPORTUNITY

Modernizing our data infrastructure will provide more effective ways to access data and digital services that can support more complex and vibrant data ecosystems, based on open standards that facilitate collaboration and are available anytime, anywhere and from any device paradigm. Facilitating the access and discoverability of HC key data assets will enable a priority-driven and agile approach to data analytics that supports decision-making. Taking this further by identifying and adopting innovative technologies would create new opportunities for our programs and services, and perhaps close some of the current gaps in our current toolset.



Data and digital technologies should be viewed as closely coupled and the combination of the two together can unlock latent value in our data. Our digital strategies should emerge from experimentation, learning, the needs of staff, and working closely with end-users to better understand what they truly value. There is a need to pilot innovative solutions and document new approaches to secure data and address privacy concerns at an enterprise level. In order to realize the vision of an agile and adaptive organisation, we will need systems in place that will enable the department to integrate, visualize, and operationalize data from diverse information sources to support evolving policy requirements, real-world effectiveness and regulatory decision-making.

Exploration and experimentation with artificial intelligence and machine learning to analyze large and complex data sources with new methods will lead to new insights. The same technology can be explored to find new methods to de-identify and anonymize data and allow scientists and analysts to run queries against data and receive only de-identified aggregate results.

Data users often do not know that the data they are looking for is available within the department. Avoiding this scenario requires ensuring that data is captured in an inventory, and is discoverable and accessible. Through proper access, Health Canada can leverage its vast amount of data for new insights. Health Canada staff will be able to analyze and extract insights from data more efficiently and in a timely manner to improve decision-making. Improving data accessibility and quality will enhance interoperability, usability, and the ability of Health Canada to share valuable data resources internally and externally. This in turn will enable advanced data analytics capabilities to inform policy, program and administrative decision-making.

Establishing data models, data interoperability standards, flexible solutions like Application Program Interfaces (APIs), and user design principles will support internal interoperability and allow Health Canada to more efficiently provide external stakeholders with data to support the health care system and potentially innovative reuse. APIs are foundational to a modern digital ecosystem, and following the Government of Canada Digital Standards for APIs will support integrated digital processes across departments and agencies.

Implementation

This Data Strategy is a starting point; it outlines a commitment to implementing the vision, principles and strategic framework that will lead to the ultimate outcome of using data as an asset. The **Health Canada Data Strategy Multi-year Roadmap**, the plan that will guide departmental data work in the years to come, needs to be carefully planned in collaboration with all the branches. From a corporate services perspective, the Roadmap will identify opportunities for enterprise approaches that meet common business needs of the department.

Table 2 below summarizes the high-level strategic actions under each framework section identified in this Data Strategy that will need to be supported by the entire department, with executive leads providing leadership. These strategic actions will be the basis to co-design the Data Strategy Multi-year Roadmap.



TABLE 2. Data Strategy Framework Actions

STRATEGIC FRAMEWORK SECTION	ACTION
	Engage department on the data talent and capacity needs and assess the current state of data literacy and competencies.
People and Culture	Promote data awareness across the department, showcasing Government of Canada data stories.
Guiture	Leverage Health Canada's DM Solutions Fund for data experimentation projects.
	Establish data talent development plans and recruitment strategies to address talent gaps.
	Leverage governance to ensure the required level of data oversight, clearly defining data roles and responsibilities and designated accountabilities for decision-making around data.
	Leverage frameworks and standards for data privacy, ethics and security leveraging the government wide communities.
Governance	Identify key data initiatives to bring to governance, learning and adapting the governance process for data by applying lessons learned and best practices.
	Develop and implement a Health Canada Information Reference Model.
	Integrate privacy, security and ethics considerations into the design and governance of data.
Environment and Digital Infrastructure	Continue to leverage and integrate enterprise architecture into the design of digital data systems.
	Engage Health Canada branches to assess their unique digital and data infrastructure needs and assess the current gaps and opportunities.
	Establish a common set of enterprise data needs and supporting enterprise data tools.
	Establish enterprise-level data discussion forums and communities of practices to facilitate communication.
Communications	Establish data collaboration relationships with federal, provincial, territorial and Indigenous partners.
	Engage with stakeholders to find out which Health Canada datasets are of highest interest and value to them.

The immediate next steps include launching the Data Strategy and developing the Health Canada Data Strategy Roadmap. These activities will be led by CSB, BREAD and include the following:

- Identify and assess governance roles and responsibilities, starting immediately with those of a Chief Data Officer, to determine which of the existing structures are best suited to provide oversight to data.
- Tap into departmental and CSPS learning services to promote available data literacy opportunities for employees.
- Identify early infrastructure partnership opportunities that programs might leverage.
- Build momentum and interest at all levels for establishing a data-driven culture through open houses and communications, including a launch event and data roadshow.
- Incorporate a data lens into the Enterprise Architecture review of IP projects, and continue developing a departmental Information Reference Model that will offer an at-a-glance view of departmental data, and serve as a starting point for data design.
- Accelerate concrete actions, including leveraging the DM Solutions Fund, to harness
 the value in the data we have, such as through data analytics to develop insights from
 existing data sets to support branch business needs.
- Increase public access to data and information.
- Work with branches and internal services providers to co-develop a multi-year Health Canada Data Strategy Roadmap to support implementation.

The Health Canada Data Strategy also calls upon branches to apply a data lens to their mandate and the programs they deliver, in addition to supporting an overall enterprise approach to data. Building a culture where data is managed, shared and leveraged in accordance with privacy, security and ethics, will increase the confidence Canadians have in our ability to maintain and improve their health. To do this, branches are encouraged to:

- Showcase data success stories and share lessons learned, best practices and opportunities to leverage data as an asset.
- Use demo projects to establish branch practices for leveraging data as an asset.
- Incorporate a data lens into branch governance structures and investment projects.
- Incorporating data actions into operational plans.

These early implementation actions will position Health Canada to deliver this Data Strategy in the years to come.