Plan for the Adoption, Implementation, Sustainment and Evaluation of the Canadian Cancer Clinical Trials Stakeholders Charter

*indicates a term that is defined in the Glossary referenced below

[1] referenced below

Version 1 – January 29, 2021

INTRODUCTION

This document addresses the Adoption*, Implementation*, Sustainment*, and Evaluation* (AISE) of the Canadian Cancer Clinical Trials* Stakeholders* Charter* (Charter). This Charter (Appendix 1) was created based on the premises of the Canadian Clinical Trials Transformation Initiative model (CCTTI Model)[1] which promotes Patient Centricity and acknowledges the role of the Patient Group (PG) throughout the Clinical Trial Continuum*(CTC).

The AISE of the Charter represents an innovation in methodology throughout the CCT. This initiative is intended to facilitate the institution of the Charter among all the members of the stakeholders involved in the CTC.

The existing Charter Working Group*(WG), who developed the CCTTI Model and elaborated the Charter, are now ready to engage in the process in the AISE of the Charter. To achieve this, they will recruit committed representatives of the Stakeholders' community to collaboratively:

1. Identify and address key opportunities and barriers to the AISE of the Charter process.
2. Secure resources (financial, time, material, etc.) and commitment to develop a sustainable infrastructure to support AISE of the Charter by Adopters among stakeholders along the continuum.
3. Set-up a Stewardship* process to introduce the Charter, and advocate for its eventual embedment in CT guidelines/operating practice.

GOAL

The main goals of the AISE initiative include the following:

1. To Implement the charter among all the members of each stakeholder group involved in the CT Continuum.
2. Create and put in place infrastructure, resources, and support to facilitate sustainable integration of the Charter into CT practice.

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STRATEGY

The proposed strategy is to establish collaborations among members of Stakeholder groups to work together to identify opportunities, remove barriers, create infrastructure and materials, as well as to secure resources and support thus, facilitating the AISE of the Charter.

This strategy is anchored on the acknowledgement of **the differences** in **buy-in potential**, and in the **capacity** for **implementation, and sustainability** among the Stakeholders as dictated by their constraints, particularities, sensitivities, and respective contexts.

The strategy for gaining adoption of the Charter is dependent on the following premises:

- Identification and mitigating barriers, opportunities
- Peer Influence
- Continuous Improvement/Developmental Evaluation Approach*
- Strategic Teams of Influencers*, Enablers*, etc.
- Demonstration of Benefits
- Creation of support, infrastructure, materials, and platforms
- Confirmed continuous financial needs from Sponsors*
- Use and Building on existing availability of material and resources

A Developmental Evaluation Approach* will be applied as it is best suited to allow customization, trial and application of insights in continuous improvement cycles.

ASSUMPTIONS

The success of the AISE of the Charter is based on the assumptions that Stakeholders generally accept to:

- apply the concept of patient centricity
- value of the patient group/patient perspective throughout the CTC
- be willing to include the Patient Group and/or their representatives at key interfaces throughout the continuum
- acknowledge the Patient Group voice and perspective and to include it in key decisions
- provide sponsorship (financial support, resources, IT, expertise, In-kind, etc.)

CHALLENGES - WHY

In addition to the many challenges inherent to conducting clinical research, engaging, and incorporating patients and their input as partners through the clinical trial continuum poses some unique and significant hurdles.

The following are critical and must be addressed:

1. Key interfaces (those that will deliver greatest value from patient input) and the related needs, interests, and sensitivities of the various stakeholders, are not clearly identified and articulated in the CTC.

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2. The Role and Responsibilities, Expectations and Criteria/Conditions for effective/respectful Patient Group inclusion in various contexts and are not clearly articulated nor are they widely shared.

    a. Patient Groups are not aware in what is expected of them, what they may expect, and are not familiar with the various contexts where they may contribute.
    b. The Patient Groups have limited levels of literacy about:
        i. the CTC, methods, processes, and its business dimensions, and
        ii. confidentiality, regulatory and ethics requirements.
    c. Stakeholders limited levels of literacy about the patient experience.
    d. Mutual trust and transparency need to be established among Patient Groups and other Stakeholders
    e. Stakeholders at key interfaces do not know how to effectively include Patient Groups nor do they understand their respective roles, responsibilities, and expectations for the various contexts.
    f. Resources and support to facilitate Patient Group inclusion at key interfaces are not easily accessible.

3. Committed financial and other resources and stewardship must be secured.
4. The support, training, preparation, resources, communication forums/platforms remain to be developed for both Patient Groups and Stakeholders to reach effective participation, collaboration, and partnership.
5. Mission Critical: It is difficult to find and engage Patient Groups who are equipped (trained/informed/understand the commitment, etc.) to participate throughout the CTC.
6. The common and standard understanding of the concept and requirements of patient group participation must be anchored into clinical research practice.
7. The engagement of Stakeholder needs to be secured and mobilized and enablement strategies and resources must be put in place.
8. Strategies to manage the various interests, needs, constraints and sensitivities among Stakeholders need to be developed and deployed.
9. Though some initiatives are in place to include patient groups in the CTC, they lack consistency and monitoring.

SOLUTION - HOW

Critical to the success of this mission is the establishment of teams/collaborations of committed representatives among the various Stakeholders who are adept and dedicated to guide, provide insight, influence, and secure resources (financial and others). An overall Stewardship team will need to be created to spearhead and manage the process.

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IMPLEMENTATION PLAN OVERVIEW: STEPS/REQUIREMENTS TO ACHIEVE THE GOAL

LIST OF STEPS

1	Elaborate a Strategy and Plan to Implement the Charter and to Evaluate the implementation
2	Secure Resources and Set-up Infrastructure as outlined in Plan
3	Identify and Suggest Solutions to Address Key Barriers and Opportunities
4	Create and Deliver Resources/Solutions to address Barriers and Opportunities
5	Promote and Gain-Buy-in For Charter and its implantation
6	Execute Pilot Implementation, Evaluation, Data Collection, Analysis and Recommend Amendments
7	Amend Implementation Process and Materials based on Pilot Report
8	Launch Wide Implementation
9	Evaluate and Report
10	Publish (Charter, Implementation Plan, Evaluation of Implementation and Results, Resources, Training Programs and Support)

DESCRIPTION OF STEPS

1. *Elaborate Strategies and Plans to Implement the Charter and to Evaluate the implementation*

Deliverables

- Draft of Implementation and Evaluation Strategies and Plans
- Presentation of Draft Strategies and Plans by WG at the CCC CT October 21, 2020 meeting and collection of recommendations
- Validation of draft Strategies and Plans (including recommendations from conference) among representative stakeholders.
- Version 1 of Implementation and Evaluation Strategies and Plans (revised versions will be created as the AISE program develops according to the Developmental Evaluation Approach ii is based on).

Outcomes

- **Working Group** [i]is empowered with final versions of Strategies and Plans to
- to be used to launch the process **Nov. 1, 2020**

2. Secure Resources and Set-up Infrastructure as outlined in Plans

Deliverables

Outcomes

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- **Stewardship[ii] Team** *(ST)– Prepared to lead and oversee initiatives*
- ***Working Committees[iii]*** *(WCs)*
- *List of resources and infrastructure*
- *Budget, resources, IT, Platforms[iv], Training, Databases, etc. necessary to support implementation*
- *Secured and set-up Resources and Infrastructure*
- *All teams are established and prepared to secure required structure, solutions, and resources (Financial, Infrastructure, Materials, Training, Databases, Forums, etc.) to meet the needs of AISE*
- *Resources, Infrastructure and Support in place*

Please note*: Steps 3 – 5 may occur concurrently depending on each particular Stakeholder's readiness to buy in to the AISE program.*

3. *Identify and Suggest Solutions to Address Key Barriers and Opportunities*

Deliverables

- Survey and Stakeholder Survey Results identifying barriers, opportunities, and solutions to address Stakeholder needs and interest -within their respective communities and contexts
- Suggested Solutions and ways to implement them
- Engaged ST and WCs to create and implement solutions
- Outlined material and processes to train and inform Patient Groups
- Identified requirements to prepare Patient Groups to serve as representatives and other Stakeholders

Outcomes

- Stakeholders **u**nderstand, communicate, and address the needs, interests, and sensitivities of the various Stakeholders and their contexts
- Stakeholders agree that patients have equal standing/rights in the decision processes across the CT continuum
- Patients are equipped to fulfill role as informed partner at CTC decision tables
- All Stakeholder group members are equipped and sensitized to welcome and integrate Patient Group participation and related paradigms
- The framework and structure are ready support the various Stakeholder groups to effectively integrate Patient's participation

4. *Create and Deliver Resources and Solutions to address Barriers and Opportunities, and to support Implementation and Evaluation*

Deliverables

- ST and WCs ready to produce resources and solutions
- Training Programs and delivery strategy for Each Stakeholder Group
- Database facilitating access to patients
- Material and Resources
- Discussion and Support Platform/Forums

Outcomes

- All elements are set-up for Stakeholders to fulfill their respective roles
- Infrastructure enabled and material/resources available and hosted

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- 2-way Communication Process among Stakeholders
- Distribution Plan for training, materials, and support

Please note: *Wide implementation may be started as of step 5 based on readiness of designated organization.*

5. *Promote and Gain Buy-in for adoption and implementation of the Charter*

Deliverables

- Promotional Material and Strategies
- Identify and prepare **Enablers**[v]
- **Enablers** identify potential **Adopters**[vi]
- Articulated Strategy to gain buy-in

Outcomes

- Identified Enablers and Adopters are engaged in recruiting and enrolling participants for the pilot*.

6. *Execution of Pilot Implementation, Evaluation, Data Collection, Analysis and Recommend Amendments*

Deliverables

- List of targeted potential Adopters and a list of pilot participants
- Tailored material (as requested by pilot adopters) to meet respective Stakeholders' groups
- Sites and Participants prepared for pilot
- Pilot Launched
- Monitoring process in place
- Data collected and analyzed
- Reports and Communications
- New Adopters within each stakeholder group promoted to **Ambassadors**[vii] to lead the recruitment of Adopters in the wide implementation process
- A new **Task Force*** made up of committed Ambassadors and Adopters, selected among each shareholder group to oversee the standardization, harmonization, optimization, and advocacy of the benefits of CT Charter leading to new guidelines for the CTC

Outcomes

- The successful pilot implantation is completed, Collection and Analysis of Data complete and documented, and Recommendations for amendments to Documents, Processes and Materials are generated.
- A new Task Force is in place to ensure the AISE of the Charter influences the guidelines applied in the CTC.

7. *Amend Implementation Process and Materials based on Pilot Report*

Deliverables

Outcomes

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- Updated and more effective implementation process and related materials and resources
- Committed Task Force to promote and support implementation among peers
- Effective Communication strategy and material to engage others

- A group of experienced and committed supporters is now available to actively facilitate a smoother wide adoption.

8. Launch Wide Implementation

Deliverables

- Identify and engage partner for hosting platform for delivery, long-term management & governance of the Charter, C-CTTI and related implementation resources
- Processes, Material, Resources, and Infrastructure at scale to support wide distribution and implementation
- Critical Mass of Stakeholders (Enablers, Adopters, Ambassadors) actively promoting and supporting
- List of newly selected potential Adopters within each stakeholder group to be provided to Ambassadors

Outcomes

- A critical mass of Adopters is committed and mobilized to implement and sustain the Charter.

9. Evaluate and Report

Deliverables

- Collection of Data, KPIs, and RWE/D
- Analysis of Data
- Report and Recommendations

Outcomes

- Successful implementation of the initiative is achieved
- Information to guide future implementation, evaluation, and adoption
- Model and recommendations are influencing evolution of CT practice
- Involvement and Recognition of Patient Groups as partners throughout the CTC becoming standard of practice
- Gained understanding of the concerns of Stakeholders who may be still reluctant to adoption of the charter and identified potential solutions for them

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- Task Force working with reluctant potential Adopters to resolve issues and gain commitment

10. Publish (Charter, Implementation Plan, Evaluation of Implementation and Results, Resources, Training Program and Support)

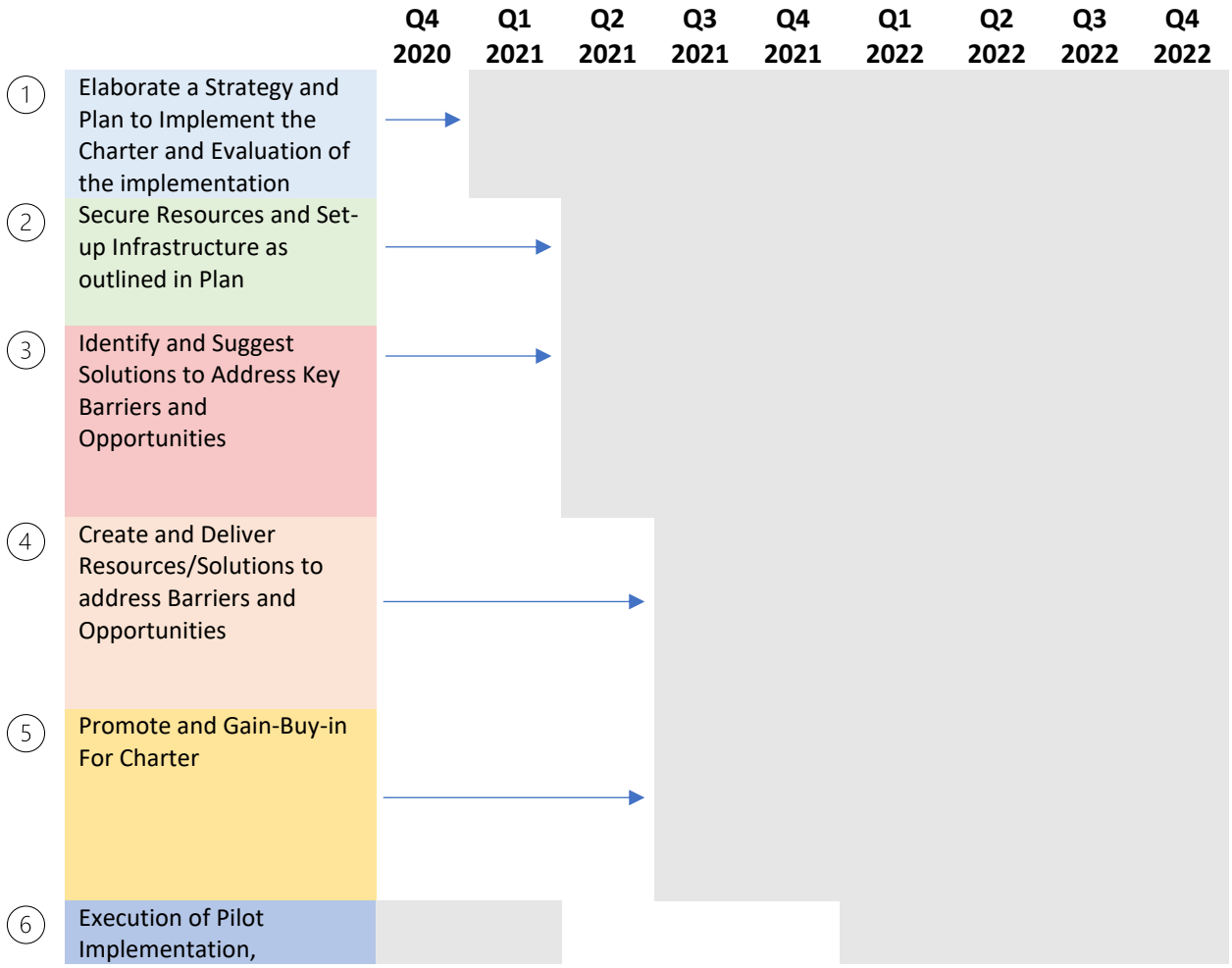
Deliverables

- Publications in peer reviewed journals, and in industry and CTC communication venues (e.g.: forums, platforms, sites, conferences, etc.)

Outcomes

- Adoption, Implementation, Sustainment, and Evaluation (AISE) of the Charter representing an innovation in (CT) methodology throughout the continuum and rendering the practice and paradigm more Patient Centric are reported on.

PROJECT AISE OF CHARTER TIMELINE



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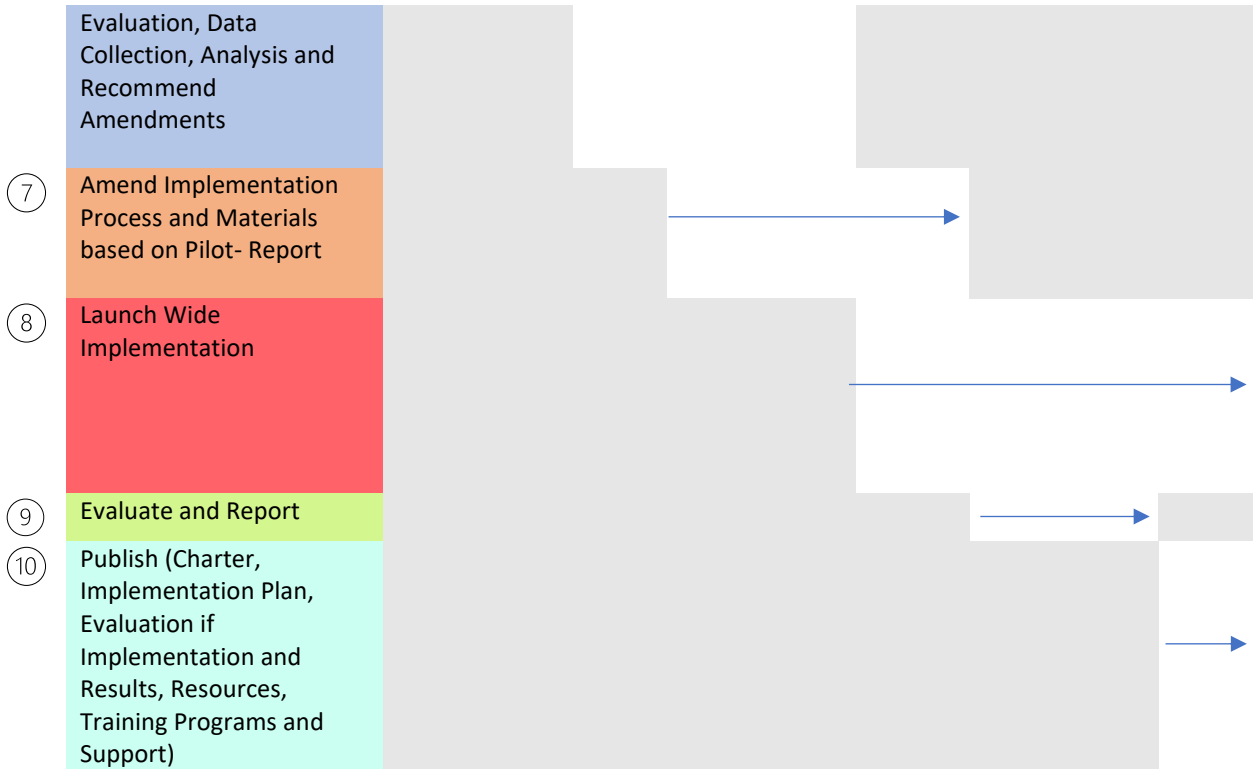

ORGANIGRAM OF TEAMS

Criteria: All teams consist of representatives of all Stakeholder

Team of Sponsors: Needed to Provide resources (Financial, Resources, IT, Expertise, In-Kind, etc.)

LIST AND COMPOSITION OF TEAMS AND THEIR MANDATE (CHART 1)

- Charter Working Group
- Stewardship Team

WORKING COMMITTEES REPORTING TO STEWARDSHIP TEAM (CHART 2)

- Financial Resources Committee
- Research
- Evaluation, Data collection and Analysis
- Communication, Documentation and Reporting
- IT and Platform
- Administrative

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CHART 1 LIST OF STEERING TEAMS

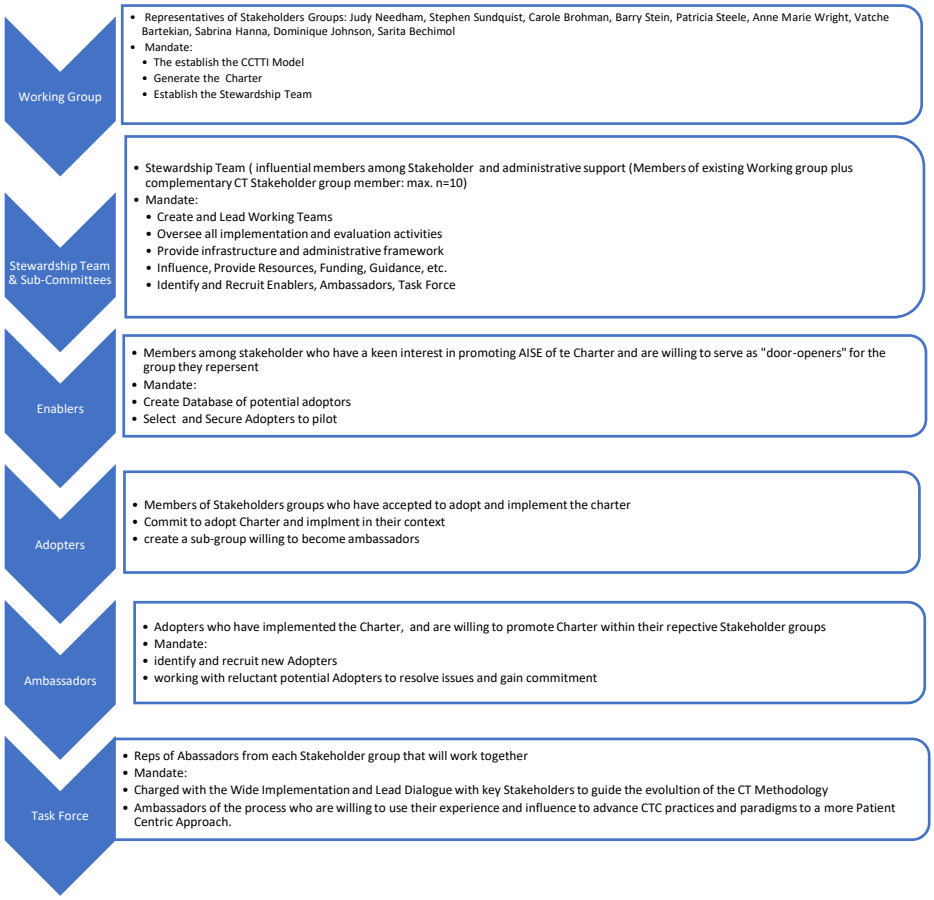

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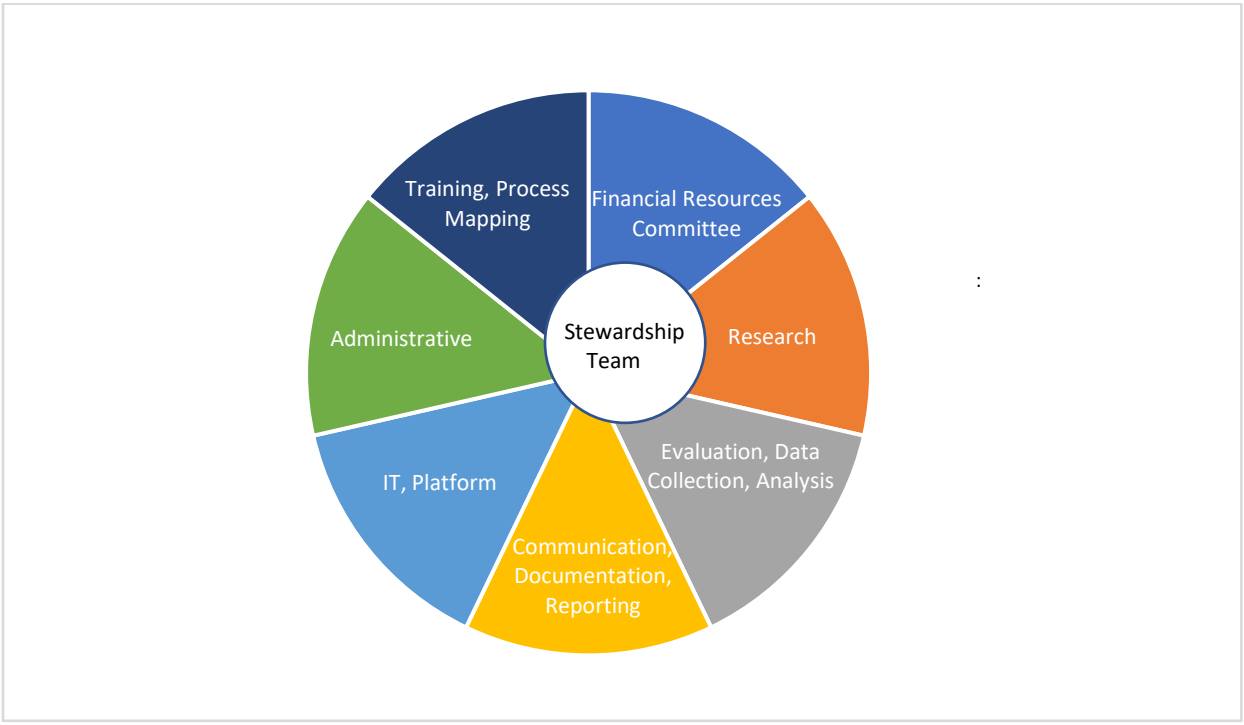
CHART 2 LIST OF WORKING COMMITTEES REPORTING TO STWEWARDSHIP TEAM



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GLOSSARY OF TERMS

- **Adoption:** The action or fact of choosing to take up, follow, or use something.
- **Ambassador**: a person who acts as a representative or promoter of a specified activity.
- **Developmental Evaluation Approach**: a method based on systems thinking that supports collecting and analyzing real-time data in ways that lead to informed and ongoing decision making as part of the design, development, and implementation process.
- **Enabler:** a person that makes something possible.
- **Evaluation**: The making of a judgment about the amount, number, or value of something; assessment.
- **Implementation:** The process of putting a decision or plan into effect; execution.
- **Influencer**: an individual or an organization that has a purported expert level of knowledge or social influence in their field, which can be used to endorse a brand's or organization's message to the larger market.
- **Key Performance Indicators (KPIs**): are the critical indicators of progress toward an intended result. KPIs provide a focus for strategic and operational improvement, create an analytical basis for decision making and help focus attention on what matters most.
- **Patient:** a person receiving or registered to receive medical treatment
- **Patient Group:** a collective group providing support, education and advocacy for a group of patients with the same or similar diagnosis or symptoms.
- **Real World Evidence:** the clinical evidence regarding the usage and potential benefits or risks of a medical product derived from analysis of real-world data (RWD).
- **Stakeholder:** an individual, group or organization with concerns or interests in an organization, endeavor, or initiative.
- **Stewardship Team**: a group of designated individuals dedicated to supervising or taking care of something, such as a project, an initiative an organization or property.
- **Sustainment:** The support or maintenance of someone or something.
- **Working Committee:** A committee established to study and report on a particular question and provide results and data requested as well as make recommendations based on its findings.

LIST OF STAKEHOLDERS

- **Contract Research Organizations (CRO):** a company that provides support for the pharmaceutical, biotechnology and medical device industries in the form of research services outsourced on a contract basis.
- **Clinical Research Units (CRU):** teams of healthcare professionals such as specially trained nurses, registered dietitians, technical and support staff, and procedural and laboratory services that offer investigators the support they need to conduct clinical research. As known as Clinical Trials Units (CTU) or Clinical Research and Trials Units (CRTU).
- **Governmental Institutions**: organizations founded for an educational, social or similar purpose, fully maintained by the government.
- **Medical Researchers**: any individual involved in research in a wide range of fields including biology, chemistry, pharmacology, and toxicology with the goal of developing new medicines or medical procedures or improving the application of those already available.
- **Patients and Patient Groups:** see definitions above
- **Pharmaceutical Companies:** a commercial business licensed to research, develop, market and/or distribute drugs, most commonly in the context of healthcare
- **Regulatory Bodies (internal/external**): organizations that are appointed by the government to establish national standards for qualifications and to ensure consistent compliance with them.

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- **Task Force:** a unit specially organized to execute a given task, formulate an integrated vision to advocate and promote it.

ACRONYMS

- **AISE:** adoption implementation sustainment evaluation
- **CCTTI:** Canadianized clinical trials transformation initiative
- **CTC**: clinical trials consortium
- **KPIs**: key performance indicators
- **PG**: patient group
- **ST**: stewardship team
- **WC**: working committee
- **WG**: working group
- **RWE**: real-world evidence

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[1] referenced below

REFERENCES

[1] Stein B. et al. (2020). CADTH Symposium. Patient Group Pathway model to Accessing Cancer Clinical Trials (Pathway Model) & The Canadian Cancer Clinical Trials Stakeholder Charter (Charter)

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APPENDIX A

File attached.

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