HEALTH CANADA

Health Product and Food Branch

Project Charter

BGTD – Screening and Review Tool (SRT)

Version: 2.0

September 14, 2016

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SECTION 1 - CHARTER INTRODUCTION

1.1 Document change control

Revision Number	date	Description	Author
0.1	July 14, 2015	Initial draft of charter	M. Houle
1.0	August 6, 2015	Approved	M. Houle
2.0	September 16, 2016	Revised version after project extension	M. Houle

1.2 Executive summary

This proposal is to enhance the screening and review processes though automation. The project will establish a suite of screening and review tools accessible through the Microsoft Word ribbon. The suite of tools would be designed to facilitate the screening and review processes by:

- autopopulating tombstone information in submission screening reports, review reports, executive summaries, records of decision, correspondence (acknowledgment, screening acceptance letter, NOC, NOL, NOD), clarifaxes and information requests at the press of a button on the basis on the submission control number;
- providing a flexible interface and storage mechanism to manage, track, trend and report on submission review issues throughout the product lifespan'
- incorporating all the BGTD-related information content of the Post-NOC guidance document and assist in the identification of changes, categorization of submissions and determination of documentation requirements through user-interaction;
- providing context sensitive information in the form of national and international guidances, points-to-consider documents, template content help, and content developed in-house (lessons learned, case studies, etc…) to support the review process; and
- providing a series user interfaces designed to allow for updating, expanding or extending the information content of the tools or the fields amenable to autopopulation.
- Providing interfaces for extracting business intelligence information from the growing database

The goal of the implementation of this suite of tools is increase review and screening efficiency and quality by reducing the need to perform repetitive tasks; by providing access to complete, up-to-date, and easily retrievable sources of information to support review and screening; and by creating a mechanism by which new information content can be developed and be made accessible to other reviewers and screeners in a simple, efficient and context sensitive fashion. These goals contribute to the following departmental priority: Priority IV - Continue to build an efficient, interconnected, and adaptable organization with improved processes, structures, and systems.

The project was initially submitted as a BGTD project in 2015 subsequent to a branch reserve funding call for proposals. The project was approved for extension of June 22, 2016 with an enhanced scope encompassing collaboration with TPD as they also had a proposed suite of tools. The tool is intended for deployment to all BGTD/TPD staff, but it is expected that the Screeners and Reviewers will make the most use of the suite of tools.

The BGTD tool is to be developed in phases whereby the different functional aspects of the tool will be released in a sequential order starting with the autopopulation tool, followed by the other modules as they are developed and tested.

The estimated cost for 2016 with respect to the continued development and expansion of the tools from the BGTD perspective is 245K$ which includes software development and implementation costs as well as costs associated with the deployment of the tool across multiple directorates. This sum is to be managed jointly by RMOD and BGTD.

Two proposals for the BEC-TIFF innovation fund, one from BGTD and one from TPD, were submitted to develop reviewer/screener tools. In order to reduce the risk of duplication and to promote integration between the two sets of tools, the proposals were bundled by BEC-TIFF. As a result, an additional 150K$ was allotted to the project in order to incorporate the TPD tools. This sum is to be managed by TPD. The specific objectives/tasks and reporting of the TPD portion of the project are to be described a separate project charter with dashboard reporting to be handled separately as well by the respective project managers for BGTD and TPD. Coordination of the two portions of the project (i.e. the BGTD and the TPD tools) will be assured by RMOD.

The key risk is delayed deployment by IMSD, as each rollout of the tool suite (3-4 rollouts are expected) will need to be packaged for installation onto the BGTD users PCs.

1.3 Authorizations

<table>
<tr><th colspan="2">Project Champion</th></tr>
<tr><td colspan="2">Name: Cathy Parker
Title: Director General
Organization: HPFB - BGTD

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Signature Date</td></tr>
<tr><th>Project Authority</th><th>Project Sponsor</th></tr>
<tr><td>Name: Lindsay Elmgren
Title: Director
Organization: HPFB - BGTD - CBE

_____
Signature Date</td><td>Name: Vikesh Srivastava
Title: Associate Director
Organization: HPFB - RMOD

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Signature Date</td></tr>
<tr><th>Business Manager BGTD</th><th>Project Manager BGTD</th></tr>
<tr><td>Name: Will Stevens
Title: Chief
Organization: HPFB - BGTD - BPD

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Signature Date</td><td>Name: Martin Houle
Title: Senior Biologist/Evaluator
Organization: HPFB – BGTD

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Signature Date</td></tr>
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SECTION 2 - PROJECT OVERVIEW

2.1 Project summary (BGTD)

Note: the project summary for the TPD portion of this project will be provided as an addendum to this charter.

2.1.1 Overview

The proposal consists in developing a suite of tools as an application-level add-in for Microsoft Word to facilitate screening and review. This proposal was developed in response to a business need. Indeed a considerable of time is currently devoted to repetitive tasks with little added value such as repeatedly entering tombstone information in all sorts of documents ranging from screening and review reports, executive summaries, summary basis of decisions and all manner of correspondence (acknowledgments, clarifaxes, information requests, notices, etc…). A portion of this proposal addresses this need.

Screeners are required to ascertain the submission category, and the required documentation for specific changes to chemistry and manufacturing on the basis of the “post-NOC changes guidance”. The document, although

extremely well designed and comprehensive is a 150 page document, split into 3 sections, one for each of BGTD, TPD and VDD. The document is unwieldy because of its size and also the density of the information content within. Screeners currently identify the changes by running through the applicable section of the documents, selecting, copying and pasting the relevant criteria for each of the relevant changes, then manually evaluating the submission category. Then they must select, copy and paste the relevant document requirements for each change into the review document. Finally, they must remove duplicate requirements. The screening tool proposes to partially automate this task.

Reviewers and screeners are required to integrate information from a variety of disparate sources in order to make risk based recommendations regarding the acceptability of products and changes to their manufacture, indications etc… Some attempts have been made to render this information more accessible and easily retrievable but with limited success. The current proposal addresses this need by not only making these information sources more readily available but also by allowing their retrieval in a context sensitive fashion. It is expected that in addition to reducing the amount of time required to access the information, this will also foster their use on a more regular basis. This tool will be of considerable utility as a training tool for new reviewers.
Lastly, it has been recognized that the function of reviewer requires significant on the job training and that learning is based on experience. It has also been recognized that sharing of lessons learned and issues is often limited to within the confines of product line divisions. The proposed tool offers a way for reviewers to share their experience by creating issue notes, lessons learned, or case studies for incorporation into the review tool and these will become available for viewing to all users.

In order to foster the use of the tool, we have selected to include it as a an application level add-in for Microsoft Word as this application is one of the main applications used by screeners and reviewers in the performance of their daily work tasks. The tools would be accessed as any other function in Microsoft word, i.e. by clicking icons on the Microsoft Ribbon.

The tool suite will be comprised of 5 main functional groups:

1. [**Autopopulation**] Auto population of tombstone information in documents
2. [**Screening**] Searching and navigating the Post-NOC changes guidance. Interactive controls to identify and select applicable changes and criteria from the post-NOC changes guidance and the necessary logic to select the change category and the required documents to support the proposed change based on user input. Functionality to output a formatted text directly to the review or screening report listing the applicable changes, the criteria and their status (met or unmet), the submission type, and a list of required documents applicable to the submission.
3. [**Documentation Access and Management**] Searching and retrieving documents from a complete library of internal and external documents such as procedures, guidance documents, points to consider documents, content help information for CTD sections, and other content developed in-house (lessons learned, case studies, issues of note, etc…). Content can be filtered or prioritized by product line (e.g. recombinant products vs plasma derived products have different requirements and different applicable guidance) or displayed in a context sensitive manner (e.g. only information relevant to the specific CTD section currently in the selection range of the current open document). Updating and adding data content can be performed using a built-in interface.
4. [**Submission Issues Management**] The module will allow for management of issues encountered during review. Initially, issues flagged by reviewers/screeners will be stored locally (i.e. inside the docx format as XML data). Issue categorisation, flow and resolution will be saved to the SRT database. Thus allowing issues to be managed in a holistic fashion as well as allowing for tracking, trending and retrieval through the business reporting tool.
5. [**Business Reporting**] The module will allow for flexible access to information stored within the BGTD databases. This will include a wizard to help develop queries against the SRT, DPD and DSTS databases. A storage mechanism will be developed for the queries so that queries can be re-used. The reports will be exported to Excel or other suitable formats.

2.1.2 Detailed description of requirements and functionality

The auto population tool:

- Requirements
  - Connection to a reliable base data source for tombstone information
  - Connection to a local secure database to store tombstone information after initial retrieval and any other information which we need to propagate after creation (e.g. review summary), and to store active controlled content field titles and their associated connection information to the source data information (e.g. DSTS connection string, field name, etc…)
  - A Word document with controlled content fields with names that match those configured in the local database.
- Functions:
  - Auto populate
    - The application-level add-in will establish a secure connection to a local database.
    - Obtain a list of content controlled field names and the data sources.
    - Scan the document for content controlled fields with these names.
    - For those fields found, initiate a connection to the relevant data source(s) and retrieve data for the relevant control number.
    - Populate the fields from the retrieved data.
  - Save
    - Scan the document for content controlled fields with names matching those in the local database.
    - Save updated or new data to the local database (e.g. non-tombstone data)
  - Add, remove, edit auto populated field(s)
    - A user with administrative privileges will be capable of modifying the underlying data through a specially designed interface.

The Screening tool:

- Requirements
  - Connection to a local secure database which stores the Post-NOC changes guidance document information in a structured manner including links and associations between changes, criteria, submission classification and documentation requirements
  - For the Screen function, a populated control number field is required on the template.
- Functions
  - Search
    - A User form or custom task pane will allow for entering search terms and advanced searching options such as limiting scope of search to changes, criteria, classification, or documentation requirements.
    - The add-in will execute a query on the database on the basis of the search terms and display the associated changes, criteria or requirements depending on selection
  - Navigate
    - A User form or custom task pane will display the post-NOC changes guidance information in a tree view display with the possibility of filtering based on terms (e.g. DP, DS, controls, etc…).
  - Screen
    - After pressing the “screen” button, the user will be directed through a set of user interactions whereby one will search and/or select applicable changes and select the criteria which were met for these changes.
    - A formatted text block will then be inserted into the document at the selection point which will include the list of changes, the list of criteria for each change, which were met or unmet, the list of required documents (with duplicates removed) and the submission type.
  - Update Post-NOC Changes Data (upon revision of the guidance)

        - A user with administrative privileges will be capable of modifying the underlying data through an interface which reproduces the format used in the Post-NOC changes guidance.

The Review tool:

- Requirements
    - Connection to a local secure database which stores the documents, the information content, the linkages, the context tags, etc…
    - There are no special requirements with respect to the open word document to search through or navigate the content, furthermore some basic filter options will be also available (product line, DS vs. DP, etc…)
    - For content to be displayed in a context sensitive fashion, the word document must contain bookmarks or headers named according to the CTD nomenclature.
- Functions
    - Search
        - A User form or custom task pane will allow for entering search terms and advanced searching option such as limiting scope of search based on filter options
        - The add-in will execute a query on the database on the basis of the search terms and display a list of relevant search results. Clicking on a listed item will open the document either in its parent application (e.g. PDF reader) or in a user form if it is simple text.
    - Navigate
        - A User form or custom task pane will display the list of documents in a tree view display with the possibility of filtering based on terms (e.g. ICH, FDA, HC, in-house). Clicking on a listed item will open the document either in its parent application (e.g. PDF reader) or in a user form if it is simple text.
    - Context Sensitive Display
        - With the context sensitive display custom task pane open, information content will be restricted or prioritized based on a selected product line and based on the location of the cursor in the document. The add-in will identify relevant content by matching it to the first bookmark or heading up from the cursor (e.g. if the previous heading is 3.2.P.8, the list of documents and content help related to stability will be displayed).
        - Clicking on a listed document will open it.
    - Apply Bookmarks
        - Given that the context sensitive display is dependent on bookmarks, a function will be available to scan the document and apply bookmarks to lines of text which have the hallmarks of being CTD headers.
    - Submit revisions, additions, obsolescence
        - All users will have the capability of contributing to the content of the review tool by authoring changes and/or additions through an intuitive interface which will capture the changes/additions as well as structure data (e.g. tags) to allow for effective searching and context sensitive display of the documents and/or information. Contributed changes will be specially identified until vetted and approved by an administrative user
    - Approve revisions, additions, obsolescence
        - A user with administrative privileges will be capable or approving contributed additions or changes.

Issues Management:

- Requirements
    - A word document template with a populated control number field is required.
    - For committing issues to the database, a connection to a local secure database to store the Issue information and subsequent resolution and flow

- Functions
    - Create Issue
        - A User form or custom task pane will allow for flagging issues and associating them with a particular control number, user and function (screen, 1rst review clinical/C&M, 2nd review clinical/C&M, executive review clinical/C&M, post-NOC/NOL, or OSE). The issue will be also associated to a specific location in review document via a location tag. The issues will be stored locally in the XML data of the document until committed to the database by the user. Issues will be tagged with additional meta data such as: relevant CTD section, collection of tag words, issue type and category, thus enabling subsequent business intelligence reporting.
    - Issue Resolution Flow
        - Interfaces will allow users to resolve issues locally (never committed to database), track resolution through information requests to the sponsors, or external expertise to a final decision on issue outcome. Issues can be completely closed or remain open as commitments which can then be tracked through the business intelligence reporting tools.
    - Clarifax generation
        - At the users request, all issues marked with readied information requests will be scanned to generate an information request list in the database which will then be available for retrieval through a template for review and approval by a manager and subsequent issuance by the regulatory affairs group.

Business Intelligence Reporting:

- Requirements
    - A secure connection to the SRT, DSTS and DPD databases

- Functions
    - Create Queries
        - Queries joining data from the DSTS, DPD and SRT database will be create through a wizard type interface
    - Manage Queries
        - Developed queries can be stored, retrieved, copied and modified
    - Execute Queries
        - Queries can be executed and the data exported to Excel or another suitable format.

Data Integrity and Safety Measures:

- Limit capability to modify some fields (auto population tool) to categories of users.
- Access restrictions to the database will be controlled by user names and passwords. All the requirements of IT Security document (RDIMS# 206846) are met. Administrators will be able to login directly into the software in order to provide support directly at a user's computer.
- Ability to report bugs directly through the add-in.

Performance measurement:

- Requirements
    - Counter for fields autopopulated, reference documents accessed, semi-automated screenings, content generated and accessed, and Issues tracked.

2.2 Project goals, business outcomes, and objectives

No.	Goals	Objectives	Business Outcomes
1	Reduce or eliminate repetitive tombstone data entry	A modern workplace that makes smart use of new technologies to improve networking, access to data and customer service. We will pursue affordable, **interoperable tools and systems, and emphasize a tech-savvy and responsive culture** that puts citizens first, making investments that are appropriate to sound public finances and the concrete needs of Canadians.[1]	Rollout auto population tool
2	Partially automate the screening process		Rollout of the screening tool
3	Facilitate access to supporting information required for screening and review		Rollout of the review tool
4	Provide an efficient and accessible means for the development, storage, retrieval and sharing of information content to support submission screening and review	A capable, confident and high-performing workforce that embraces new ways of working and mobilizing the diversity of talent to serve the country's evolving needs. We will stress the importance of competent, engaged and productive leaders, managers and employees. We will also focus on **the value of knowledge as well as learning from the collective experience in developing evidence-based options for decision-makers**.[1]	Rollout of the content management, issues management and business intelligence reporting tool

1 Blueprint 2020 - A Vision for Canada's Federal Public Service

2.3 Project scope

2.3.1 Scope definition

The project includes the following activities:

1. Development of the application level add-in for Microsoft Word with the functionalities outlined above.
2. Development of a database structure to hold the configuration data and information, the post-NOC guidance information and linkages, the resource documents and necessary linkages, and the in-house generated content.
3. Import of already available data content, information and resource documents into the database

2.3.2 Boundaries

Activities in Scope	Activities out of Scope
• Development of the application level add-in for Microsoft Word • Development of a database to hold the content • Identifying a means to connect to a reliable data source for tombstone information • Import of already available data content, information and resource documents into the database • Development of new content • Development of templates for use with the suite • User training	

2.4 Milestones

2.4.1 BGTD

Project Milestones	Description	Expected Date
Project Charter	Signing of Project Charter v2.0	2016-09-30
Phase 1 Rollout	Suite including: • autopopulation tool add-in final release • Screening tool add-in beta release • documentation access tool add-in beta release	2016-10-15
Phase 2 Rollout	Suite including: • Screening tool add-in final release • documentation access tool add-in final release • Issues management Beta • Business reporting beta	2017-01-15
Phase 3 Rollout	Complete suite rollout	2017-03-30

2.4.2 TPD

2.5 Deliverables

Legend:
Tasks linked to the autopopulation tool
Tasks linked to the Screening tool
Tasks linked to the documentation access tool
Tasks linked to the Issues management tool
Tasks linked to the Business reporting tool

Deliverable	Module	Reponsibility	Target Date
Define initial user requirements (feature list)	Autopopulation	SME[1]	Complete
Design rudimentary interface	Autopopulation	PM[2]/TR[3]	Complete
Design database elements structure	Autopopulation	PM/TR	Complete
Develop proof of concept basic implementation	Autopopulation	PM/TR	Complete
Revise user requirements	Autopopulation	SME	Complete
Redesign user interface	Autopopulation	SME	Complete
Prepare draft integration test list (test all features)	Autopopulation	SME	Complete
Develop working alpha module	Autopopulation	PM/TR	Complete
Multiple cycle test-debug-refactor stage 1	Autopopulation	SME/PM/TR	Complete
Finalize integration test list	Autopopulation	SME	Complete
Develop working beta module	Autopopulation	PM/TR	Complete
Multiple cycle test-debug-refactor stage 2	Autopopulation	SME/PM/TR	Complete
Finalize version 1 module	Autopopulation	PM/TR	2016-09-31
Initiate rollout process	Autopopulation	PM	2016-09-31
Develop user documentation/training material	Autopopulation	SME	2016-10-30
Complete Rollout to BGTD (PHASE 1)	Autopopulation	IMSD[4]/SSC[5]	2016-10-30
Train users	Autopopulation	SME	2016-10-30
Complete Rollout to other directorates	Autopopulation	PM/TR	2017-01-30
Define initial user requirements (feature list)	Screening Tool	SME	Complete
Design rudimentary interface	Screening Tool	PM/TR	Complete
Design database elements structure	Screening Tool	PM/TR	Complete
Develop proof of concept basic implementation	Screening Tool	PM/TR	Complete
Revise user requirements	Screening Tool	SME	2016-09-31
Redesign user interface	Screening Tool	SME	2016-09-31
Prepare draft integration test list (test all features)	Screening Tool	SME	2016-09-31
Develop working alpha module	Screening Tool	PM/TR	2016-09-31
Multiple cycle test-debug-refactor stage 1	Screening Tool	SME/PM/TR	2016-10-15
Finalize integration test list	Screening Tool	SME	2016-10-15
Develop working beta module	Screening Tool	PM/TR	2016-10-30
Multiple cycle test-debug-refactor stage 2	Screening Tool	SME/PM/TR	2016-11-15
Finalize version 1 module	Screening Tool	PM/TR	2016-11-15
Initiate rollout process	Screening Tool	PM	2016-11-15
Develop user documentation/training material	Screening Tool	SME	2016-12-31
Populate DB with Data	Screening Tool	SME	2016-12-31
Complete Rollout to BGTD (PHASE 3)	Screening Tool	IMSD/SSC	2016-12-31
Train users	Screening Tool	SME	2017-01-22
Complete Rollout to other directorates	Screening Tool	PM/TR	2017-03-31
Define initial user requirements (feature list)	Documentation Access Tool	SME	Complete
Design rudimentary interface	Documentation Access Tool	PM/TR	Complete
Design database elements structure	Documentation Access Tool	PM/TR	Complete
Develop proof of concept basic implementation	Documentation Access Tool	PM/TR	Complete
Revise user requirements	Documentation Access Tool	SME	2016-09-30
Redesign user interface	Documentation Access Tool	SME	2016-09-30
Prepare draft integration test list (test all features)	Documentation Access Tool	SME	2016-10-31

Develop working alpha module	Documentation Access Tool	PM/TR	2016-08-31
Multiple cycle test-debug-refactor stage 1	Documentation Access Tool	SME/PM/TR	2016-11-15
Finalize integration test list	Documentation Access Tool	SME	2016-09-15
Develop working beta module	Documentation Access Tool	PM/TR	2016-09-30
Multiple cycle test-debug-refactor stage 2	Documentation Access Tool	SME/PM/TR	2016-12-15
Finalize version 1 module	Documentation Access Tool	PM/TR	2016-11-01
Initiate rollout process	Documentation Access Tool	PM	2016-12-01
Populate DB with Data	Documentation Access Tool	SME	2016-12-31
Develop user documentation/training material	Documentation Access Tool	SME	2016-12-31
Complete Rollout to BGTD (PHASE 2)	Documentation Access Tool	IMSD/SSC	2017-01-15
Train users	Documentation Access Tool	SME	2017-01-22
Complete Rollout to other directorates	Documentation Access Tool	PM/TR	2017-03-31
Define initial user requirements (feature list)	Issues Management Tool	SME	2016-11-15
Design rudimentary interface	Issues Management Tool	PM/TR	2016-11-30
Design database elements structure	Issues Management Tool	PM/TR	2016-11-30
Develop proof of concept basic implementation	Issues Management Tool	PM/TR	2016-12-15
Revise user requirements	Issues Management Tool	SME	2016-12-30
Redesign user interface	Issues Management Tool	SME	2016-12-30
Prepare draft integration test list (test all features)	Issues Management Tool	SME	2017-01-15
Develop working alpha module	Issues Management Tool	PM/TR	2017-01-15
Multiple cycle test-debug-refactor stage 1	Issues Management Tool	SME/PM/TR	2017-01-30
Finalize integration test list	Issues Management Tool	SME	2017-01-30
Develop working beta module	Issues Management Tool	PM/TR	2017-02-15
Multiple cycle test-debug-refactor stage 2	Issues Management Tool	SME/PM/TR	2017-03-01
Finalize version 1 module	Issues Management Tool	PM/TR	2017-03-01
Initiate rollout process	Issues Management Tool	PM	2017-03-01
Develop user documentation/training material	Issues Management Tool	SME	2017-03-30
Complete Rollout to BGTD (PHASE 4)	Issues Management Tool	IMSD/SSC	2017-03-30
Train users	Issues Management Tool	SME	2017-03-30
Complete Rollout to other directorates	Issues Management Tool	PM/TR	2017-06-31
Define initial user requirements (feature list)	Business Reporting Tool	SME	2016-11-15
Design rudimentary interface	Business Reporting Tool	PM/TR	2016-11-30
Design database elements structure	Business Reporting Tool	PM/TR	2016-11-30
Develop proof of concept basic implementation	Business Reporting Tool	PM/TR	2016-12-15
Revise user requirements	Business Reporting Tool	SME	2016-12-30
Redesign user interface	Business Reporting Tool	SME	2016-12-30
Prepare draft integration test list (test all features)	Business Reporting Tool	SME	2017-01-15
Develop working alpha module	Business Reporting Tool	PM/TR	2017-01-15
Multiple cycle test-debug-refactor stage 1	Business Reporting Tool	SME/PM/TR	2017-01-30
Finalize integration test list	Business Reporting Tool	SME	2017-01-30
Develop working beta module	Business Reporting Tool	PM/TR	2017-02-15
Multiple cycle test-debug-refactor stage 2	Business Reporting Tool	SME/PM/TR	2017-03-01
Finalize version 1 module	Business Reporting Tool	PM/TR	2017-03-01
Initiate rollout process	Business Reporting Tool	PM	2017-03-01
Develop user documentation/training material	Business Reporting Tool	SME	2017-03-30
Complete Rollout to BGTD (PHASE 5)	Business Reporting Tool	IMSD/SSC	2017-03-30
Train users	Business Reporting Tool	SME	2017-03-30
Complete Rollout to other directorates	Business Reporting Tool	PM/TR	2017-06-31

[1] SME: Subject Matter Experts Team
[2] PM: Project Manager
[3] TR: Technical Resource
[4] IMSD: Information Management Services Directorate
[5] SSC: Shared Services Canada

2.6 Project cost estimate and sources of funding

2.6.1 Project cost estimate

The overall project cost estimate is 395000$. For the BGTD managed portion of the project, the cost estimate is 245000$. The funds are to be used to be used for a task authorization at 800$/day (approximately 200 days), to hire students and to maintain computer systems to be used for the software development and testing.
Note: The project cost estimate is 150000$ for the TPD tools portion of the overall project. For further details regarding the use of funds, see the TPD project charter.

2.6.2 Sources of funding

The source of funding is a Branch reserve fund.

2.7 Dependencies

Dependency description	Critical Date	Contact
Deployment of MS Word application level add-in to users via IMSD/SSC	Multiple	Mike Thompson

All other dependencies were resolved during the previous year.

2.8 Project risks, assumptions, and constraints

2.8.1 Risks

No technological or infrastructure related risks remain after the first year of this project. All remaining risks are related to human resource availability

Dependency description	Probability (H/M/L)	Impact (H/M/L)	Mitigation
Delays in development and implementation due to low availability of business transformation analyst and/or in-house subject matter experts	M	H	Hiring of a student as an additional resource
Unplanned significant changes to network connectivity infrastructure	L	M	RMOD engagement with IMSD/SSC

2.8.2 Assumptions

N/A

2.8.3 Constraints

No.	Category	Constraints
1	Budget	Must respect budget
2	Scope	Project is to be rolled out using a staged approach with a pilot phase conducted in BGTD for each phase

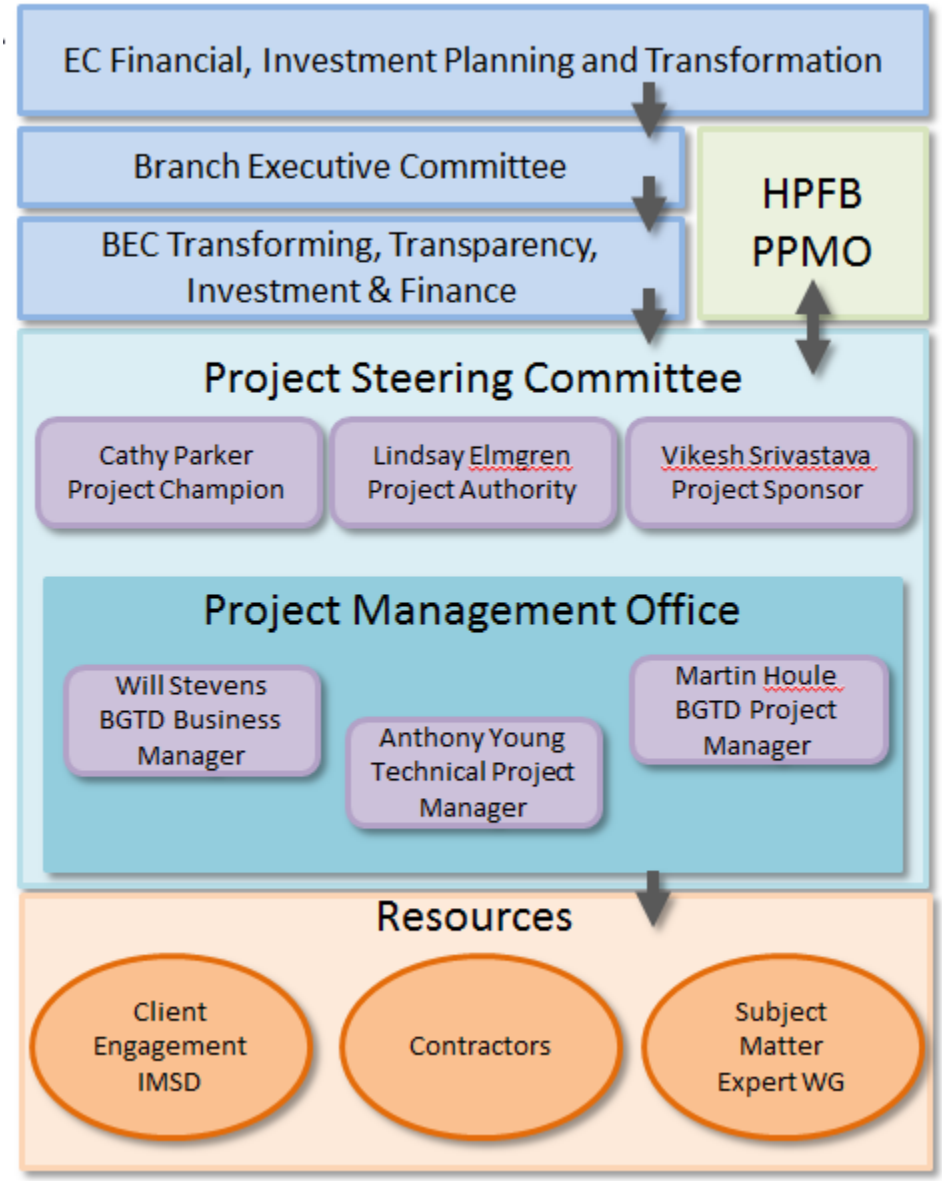
SECTION 3 - PROJECT ORGANIZATION

3.1 Project governance

The governance of this project is described in the HPFB Project Management Framework for IM/IT Enabled Projects. The governance structure has been modified to accommodate the fact that this project is not an HPFB Investment Plan project and there are no requirements to report to the Departmental Project Management Office (DPMO) or the DG IP Governance Committee. The project will be managed at the Branch level under the BEC Sub-Committee structure.

The status of this project will be tracked using HC's Project Management Framework Dashboards (on a bi-weekly basis reporting into the HPFB Portfolio Project Management Office.

3.2 Project team structure



Project Role	Responsibilities
HPFB PPMO	The PPMO ensures alignment with HPFB business objectives and Treasury Board Policy on Management of Projects, monitors and reports progress. The PPMO also ensures coordination between the BGTD and TPD screener/reviewer tools projects to ensure that there is no overlap and no duplication of effort.
Project Steering Committee	The Project Steering Committee sets project scope and objectives, provides project oversight, ensuring alignment with HPFB business objectives and business outcomes.
Project Management Office	Responsible for the detailed management of the project, achieving the project as scoped and planned, reporting, managing risk, completion of project documentation and managing project resources. This includes both business and technical management.
Subject Matter Expert Working Group	Verification and validation of business and technical requirements. Coordination of stakeholders.

3.3 Roles and responsibilities

Project Role	Responsibilities	Assigned to
Champion	• Provide Leadership on culture and values • Keep project aligned with the organization's strategy and portfolio decisions.	Cathy Parker Director General, HPFB-BGTD
Project Authority	• Own the business case • Focus on realization of benefits • Provide resources	Lindsay Elmgren Director, HPFB-BGTD-CBE
Project Sponsor	• Govern Project Risks • Manages acquisition of technical resources • Focus on Realization of outcomes • Recommend opportunities to optimize Cost/benefit • Manages engagement between technical services, IMSD and HPFB • Coordinates TPD and BGTD tools projects to ensure there is no overlap or duplication of efforts	Vikesh Srivastava, Associate Director , Business Informatics, RMOD
Business Manager BGTD	• Coordination with RMOD • Communicate business issues and risks • Manages BGTD Resources • Directs SME engagement and communications	Will Stevens Chief, HPFB-BGTD-BPD
Business Project Manager BGTD	• Coordination between BGTD assigned technical resources and the SME Team. • Monthly reporting on progress • Focus on defining and realizing user requirements for BGTD managed elements	Martin Houle Sr. Biologist/Evaluator, HPFB-BGTD-BPD
Technical Project Manager	• Coordination between RMOD and the Technical Resource • Monthly reporting on finances • Focus on providing technical environment for success	Anthony Young Special Advisor, HPFB
SME Team	• Develop and maintain user requirement specifications (URS). • Guide interface design choices. • Perform integration testing on weekly commits. • Decide when specific elements of the URS have been achieved.	Sharon Allard (GRP Rep.) Martin Houle (Project Manager BGTD) Martin Nemec (C&M Review Rep.) Vincent Panetta (ORA Rep.) Laurent Cocea (Clinical Review Rep.) Will Stevens (Business Manager)

3.4 Project facilities and resources

- Business transformation specialist with knowledge and experience in the field of visual basic.net programming and office application level add-in development.
- Business transformation specialist with knowledge and experience in the field of database programming and configuration.
- Subject matter experts in the fields of biologics submissions screening and review.
- COOP Student to provide support in software development and project management.
- VMWare configured computers for the purpose of application level add-in development and testing (4 for BGTD).

SECTION 4 - PROJECT REFERENCES

More information concerning this project can be found in the following documents:

- Branch Reserve Funding Request entitled: “Suite of Screening and Review Tools”.

SECTION 5: GLOSSARY AND ACRONYMS

Term or Acronym	Definition
SRT	Screening and Review Tools
HPFB	Health Product and Food Branch
RMOD	Resource Management and Operations Division
SME	Subject Matter Experts
TR	Technical Resource