

Issues in Emerging Health Technologies Bulletin Process

CADTH Evidence
Driven.

REVISION HISTORY

Periodically, this document will be revised as part of ongoing process improvement activities. The following version control table, as well the version number and date on the cover page, is to be updated when any updates or revisions are made.

Section	Revision Number	Date	Description/Changes Made

TABLE OF CONTENTS

Revision History.....	1
Abbreviations.....	3
1. Introduction.....	4
1.1 About Product.....	4
1.2 Scope.....	4
1.3 Audience.....	4
1.3.1 Primary Audience.....	4
1.3.2 Secondary Audience.....	4
1.4 Purpose and Application for Decision-Making.....	4
1.5 Transparency.....	5
1.6 Timelines.....	5
1.7 Roles and Responsibilities.....	6
2. Process.....	7
Process Flow Chart.....	7
2.1 Detailed Process: Technology Identification & Selection*.....	8
2.2 Detailed Process: Research and Development Phase.....	9
2.2.1 Manufacturer Engaged.....	9
2.2.2 External Reviewers Engaged.....	9
2.2.3 Internally Reviewed Literature Search.....	9
2.2.4 Information Screening & Summary.....	10
2.2.5 Bulletin Drafted.....	10
2.3 Detailed Process: Review Phase.....	11
2.3.1 Internal Review.....	11
2.3.2 External Review.....	11
2.3.3 Review Feedback.....	12
2.3.4 Final Draft.....	12
2.4 Detailed Process: Production & Dissemination Phase.....	12
2.4.1 Copy-Editing, Formatting & Translation.....	12
2.4.2 Project Owner Sign-Off.....	12
2.4.3 Web Posting & Dissemination.....	12
Appendix 1: Definitions.....	13

ABBREVIATIONS

CADTH	Canadian Agency for Drugs and Technologies in Health
ECRI	ECRI Institute
HTA	Health Technology Assessment
IEHT	Issues in Emerging Health Technologies
RCT	Randomized Control Trial
HTAIS	Health Technology Assessment Information Service

1. INTRODUCTION

1.1 About Product

Issues in Emerging Health Technologies (IEHT) bulletins are a series of concise reviews describing drug and non-drug technologies that are not yet licensed for use or widely available for clinical application in Canada. The reviewed technologies are typically expected to receive approval from Health Canada within the following six to eighteen months. Bulletins include a description of the technology, patient indications, regulatory status, adverse effects, costs, extent of diffusion, implementation issues, and a discussion of the quality of the available evidence.

The technologies described in bulletins are predicted to have a great impact, but there is no formal evaluation or statistical syntheses (meta-analyses) of the technology.

1.2 Scope

Topics suitable for IEHT bulletins include new and emerging medical technologies such as:

- drugs (including but not limited to biologics, blood products, vaccines, and prescription and non-prescription medicines)
- devices
- diagnostic tests and imaging
- medical , surgical and dental procedures
- other health care interventions

1.3 Audience

1.3.1 Primary Audience

IEHT bulletins are produced for federal, provincial, and territorial government health policy-makers and those working at regional health authorities and hospitals in Canada who make decisions about the access to or reimbursement of, medical technologies.

1.3.2 Secondary Audience

Secondary audiences include health care providers, other health technology assessment agencies and horizon scanning programs, academic researchers, professional associations, patients and patient groups, as well as the general public and the media. Interested parties can freely download or subscribe to CADTH's Issues in Emerging Health Technologies bulletins through cadth.ca.

1.4 Purpose and Application for Decision-Making

The purpose of Issues in Emerging Health Technologies is to identify and describe new or emerging health care technologies that may be important in Canada, and to estimate their potential impact on patient care and the health care system.

IEHT bulletins increase awareness of new and emerging health technologies. They provide decision-makers with an indication of the type and quality of evidence available on these technologies, allowing for better planning and prioritization in health care decisions. Health care providers and decision-makers can use IEHT bulletins to help gauge the appropriate place of new technologies and to highlight their potential risks and benefits. Patients can use IEHT bulletins to identify new technologies that may be of potential benefit to them.

IEHT bulletins do not provide recommendations for or against the use of particular health technologies, nor are they intended to replace professional medical advice. Readers are also cautioned that a lack of good quality evidence does not necessarily mean a lack of effectiveness, particularly in the case of new and emerging health technologies, for which little information is available, but which may in future prove to be effective.

1.5 Transparency

CADTH attempts to be as transparent as possible in the production of Issues in Emerging Health Technologies. The process for identifying and selecting the new and emerging technologies included in bulletins, is detailed in the publicly available Horizon Scanning Program procedures. In each IEHT bulletin the literature search methods are described, and all bulletins are freely available for those wishing to [subscribe](#). In-progress bulletins are listed on [cadth.ca](#), under the “Projects in Progress” section. Each bulletin is externally reviewed by at least two clinical experts and a manufacturer if applicable. Occasionally bulletins may be posted for stakeholder feedback.

The evidence reviewed for possible inclusion in IEHT bulletins is identified by CADTH through the following avenues:

- Published literature is identified by searching major biomedical bibliographic databases using an internally peer-reviewed search strategy. Bi-weekly search updates are run for the duration of the review.
- Grey literature (literature that is not commercially published) is identified by searching Canadian and major international health technology agency websites, horizon scanning sites, and through focused Internet searches.
- For technologies such as drugs and devices, Canadian manufacturers are contacted and given the opportunity to send studies and other relevant information.

All drafts, full literature search strategies, and working documents used to produce IEHT bulletins are archived for 15 years and may be requested if required (with the exception of copyright protected documents and information provided in confidence by customers, manufacturers or other agencies).

1.6 Timelines

Product Type	Deliverables	Approximate turnaround time
Issues in Emerging Health Technologies (IEHT bulletins)	Draft report externally peer-reviewed	10 business days
	Report finalized	4 months from topic selection to Web publication

1.7 Roles and Responsibilities

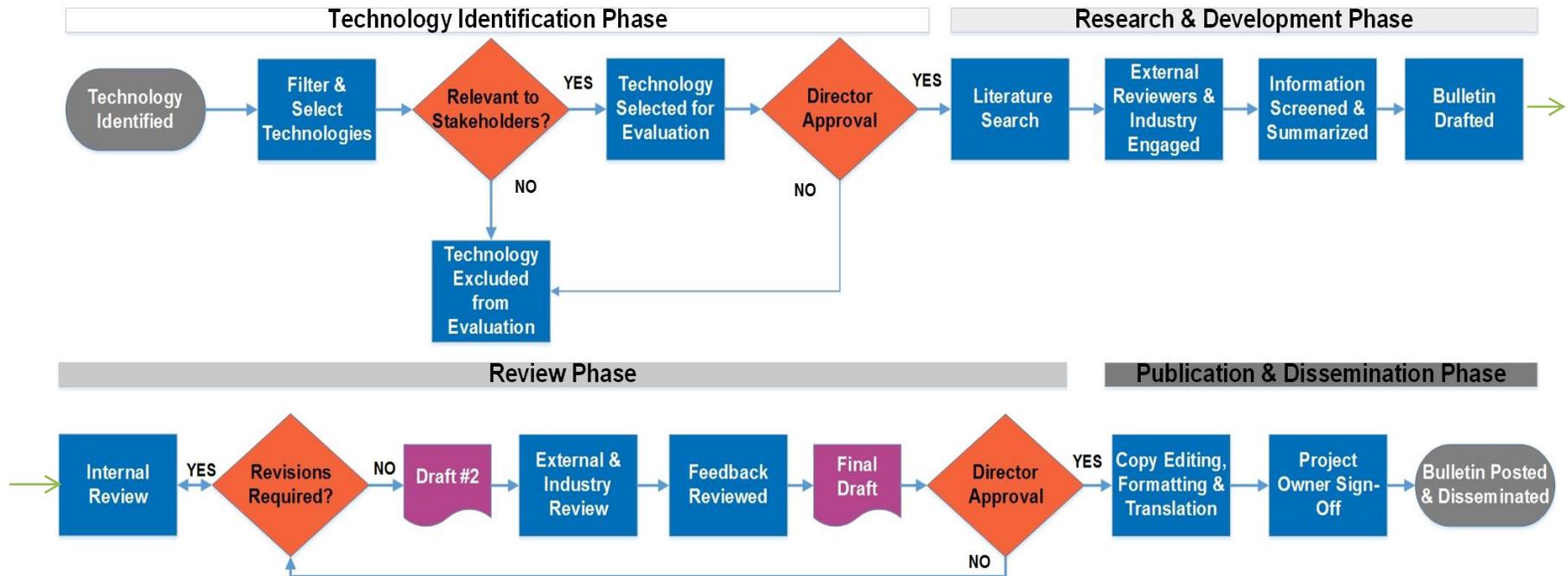
Product Type	Role	Responsibilities
Issues in Emerging Health Technologies (IEHT bulletins)	Liaison Officer	Facilitates knowledge mobilization and uptake of CADTH products.
	Project Manager	Responsible for the management of contracts and monitoring timelines and deliverables.
	Project Owner	Provides general oversight of project timelines, workload, and contract approvals; reviews report content and quality; undertakes general project risk management. The IEHT project owner is typically a Horizon Scanning Officer.
	Information Specialist	Conducts peer-reviewed literature search, coordinates search alerts for duration of review, and ensures reference citations are accurate following Citing Medicine standards. Assigns medical subject headings and keywords to document metadata.
	Author	Selects and summarizes information, drafts report and makes revisions based on peer review.
	Internal Reviewers	Review draft report, provide comments and suggest amendments. Typically reviewers include the project owner and occasionally a Scientific Advisor.
	External Reviewers	Two or more clinical experts with subject matter expertise in the specified health technology review the final draft.
	Manufacturers	Manufacturers are engaged to provide information and also to review drafts.
	Publishing Team	Responsible for copy-editing, formatting, and translating IEHT bulletins
	Scientific Advisor	Provide ad hoc guidance on matters of scientific method.
	Director, Strategic Initiatives	Approves initiation of IEHT bulletin topic and signs off on completed bulletins prior to dissemination.

* All IEHT Bulletins are also supported by CADTH's Knowledge Mobilization and Web teams.

2. PROCESS

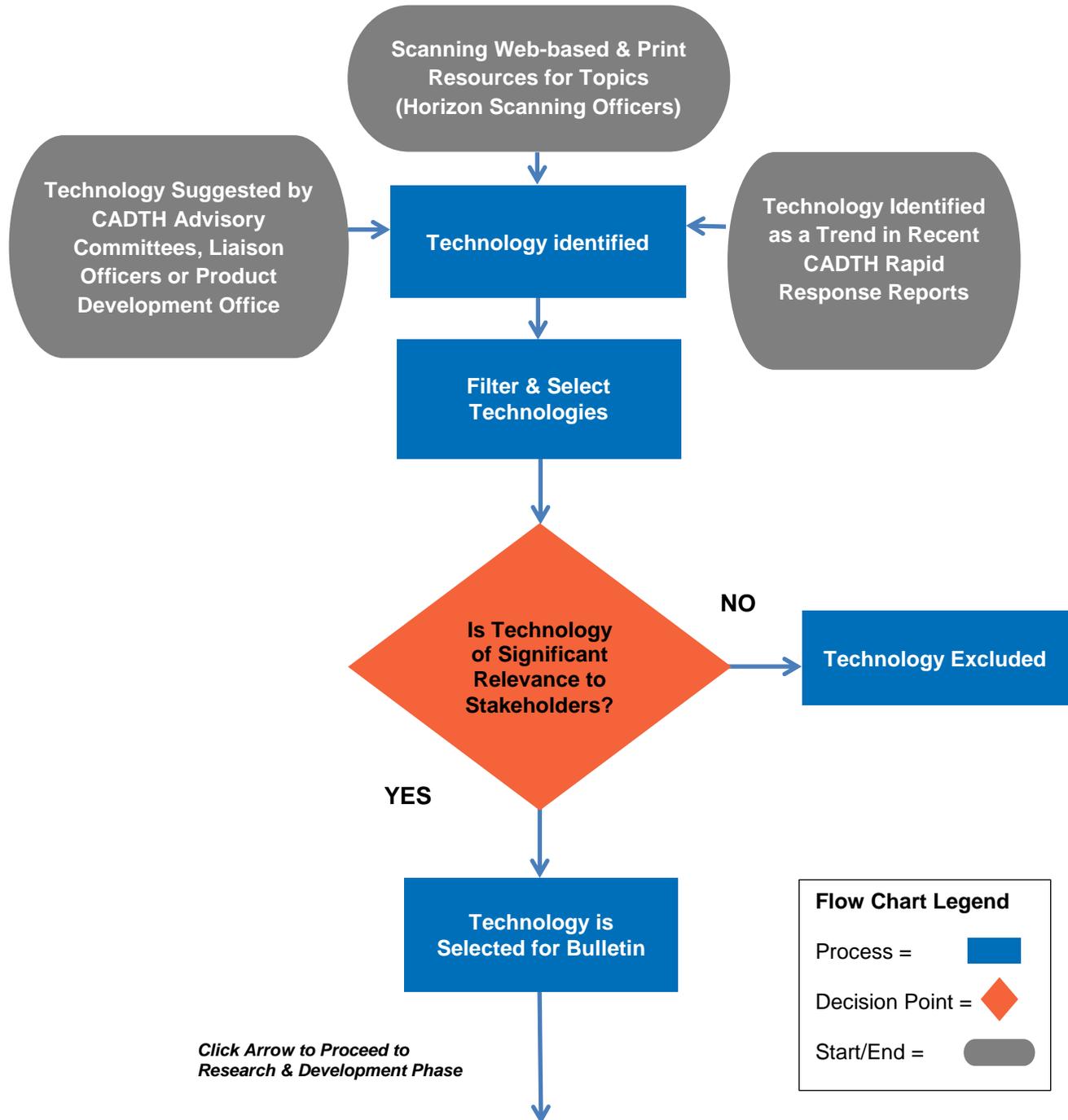
Process may be truncated to meet stakeholder needs.

Process Flow Chart



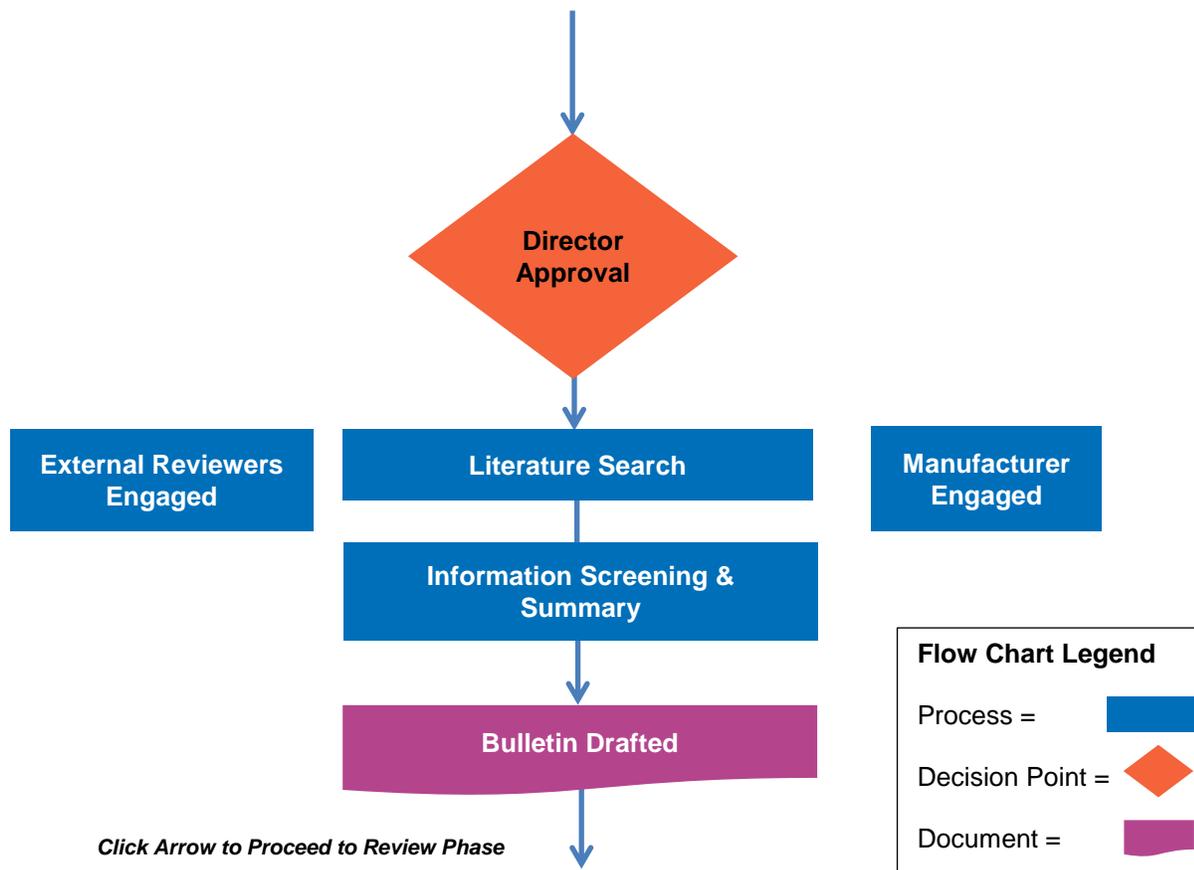
2.1 Detailed Process: Technology Identification & Selection*

*For details regarding the Technology Identification & Selection processes, please refer to the published Horizon Scanning Program process document.



2.2 Detailed Process: Research and Development Phase

* **Ctrl click** on individual processes for details



2.2.1 Manufacturer Engaged

After a technology has been identified for an IEHT bulletin and approved by the Director, Strategic Initiatives, the manufacturer associated with the technology (if there is one) is contacted by the Project Manager. The manufacturer is invited to provide CADTH with any relevant information for the evaluation. A formal letter is sent out to the manufacturer and it is given 15 days to respond. The manufacturer/developer is also invited to review a draft of the report.

2.2.2 External Reviewers Engaged

The project owner identifies potential content experts for peer review. The Project Manager coordinates the engagement of the external reviewers and ensures that conflict of interest forms are completed.

2.2.3 Internally Reviewed Literature Search

The scope and approach of the literature search is agreed upon by the Horizon Scanning Officer and Information Specialist. The internally peer-reviewed literature search is conducted using key resources including PubMed, The Cochrane Library, NIHR Centre for Reviews and Dissemination (CRD) databases, EuroScan, and the ECRI Institute. Bi-weekly search alerts are set up until the final report is published. A focused grey literature search is also conducted by searching relevant sections of the Grey Matters checklist

(<http://www.cadth.ca/en/resources/finding-evidence-is/grey-matters>). The search is typically limited to English language publications published in the last two to five years.

The Information Specialist also assigns French and English medical subject headings and keywords to the document metadata to facilitate retrieval in both official languages once the document is posted on cadth.ca.

2.2.4 Information Screening & Summary

Once the results of the literature search and any additional information provided by the manufacturer are received, the author screens the titles and abstracts and orders relevant literature (if not freely available). Article orders are sent to the Information Technician who retrieves and delivers the full text to authors according to CADTH's Access Copyright license terms. The author reviews the full-text articles selected as well as any information received from industry.

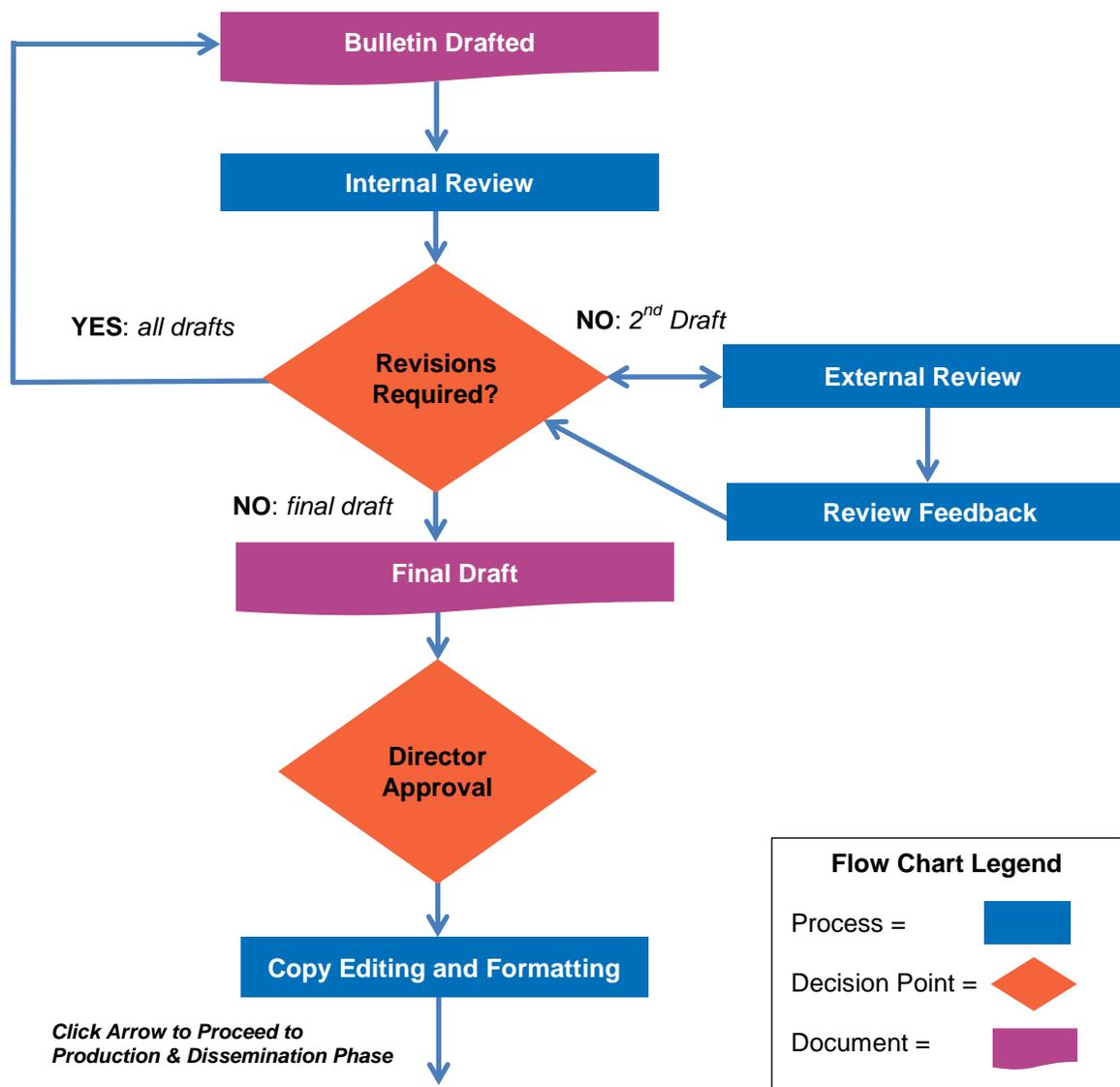
2.2.5 Bulletin Drafted

Following author guidelines for IEHT bulletins, authors summarize information describing the emerging technology, patient indications, regulatory status, adverse effects, costs, rate of diffusion, implementation issues, and the reliability and quality of the available clinical evidence. Bulletins are typically four to eight pages in length, with a summary box of key points for decision-makers.

Once the draft has been internally reviewed (see section 2.3.1), the author addresses comments and the draft report is sent out for external peer review (see section 2.3.2).

2.3 Detailed Process: Review Phase

* **Ctrl click** on individual processes for details



2.3.1 Internal Review

The draft bulletin is sent to the project owner for internal review. The project owner ensures the content is accurate and provides comments, which are sent back to the author to address. A scientific advisor may also be requested to provide specific feedback on matters related to scientific method. The revised draft is sent to the Information Specialist to ensure references are correct. If personal communications (unpublished information) have been included in the bulletin, the Information Specialist ensures all the required "permission to cite" forms have been received. All reviewers double check copyright regulations are followed.

2.3.2 External Review

External reviewer(s) (see 2.2.2) have 10 working days to complete their review. External peer reviewer(s) ensure that the bulletin accurately describes current clinical practice within the

Canadian context and that all key evidence has been included. While the external review is being conducted, the industry contact is also asked to review the bulletin (if applicable).

2.3.3 Review Feedback

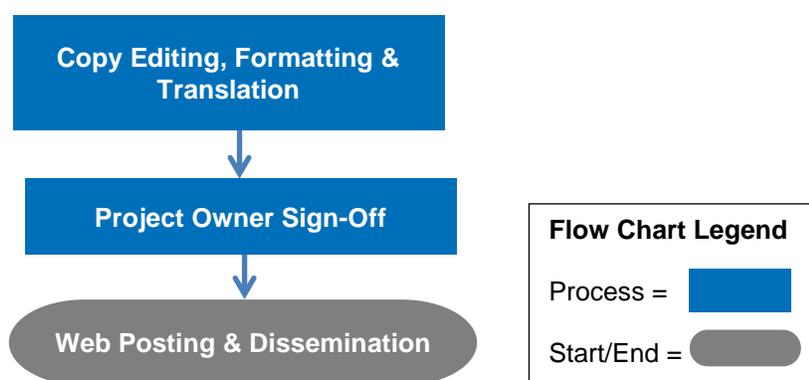
Comments from all external reviewers are forwarded to the Project Owner and Scientific Advisor who reviews the feedback and then discusses the required revisions with the author.

2.3.4 Final Draft

Once the project owner and the author are satisfied with the final draft and all revisions, it is sent back to the Information Specialist to check the references. The final IEHT bulletin draft is then reviewed and signed off by the Director, Strategic Initiatives before it is sent to Publishing.

2.4 Detailed Process: Production & Dissemination Phase

* *Ctrl click on individual processes for details*



2.4.1 Copy-Editing, Formatting & Translation

The reviewed bulletin is sent to Publishing for copy-editing, formatting, proofreading and French translation. This production stage takes approximately four weeks. The author, a Scientific Advisor and the project owner may also be consulted during this phase and will be sent a copy of the draft with all changes shown for their review. Once approved by the team, changes are incorporated by the Publishing staff. The copy-edited bulletin is sent to the Information Specialist for a final reference check.

2.4.2 Project Owner Sign-Off

Before posting the formatted bulletin, the project owner conducts a final review and signs-off on the bulletin.

2.4.3 Web Posting & Dissemination

The final bulletin is posted on cadth.ca in both official languages. An email alert is sent to bulletin subscribers informing them that a new issue is available.

APPENDIX 1: DEFINITIONS

Health Care Technology: technologies inclusive of drugs, medical devices, diagnostics (such as tests), procedures, programs and public health activities.

Horizon Scanning: systematic identification of new and emerging health technologies that have the potential to impact health, health services, and/or society and which might be considered for Health Technology Assessment.

New: a health technology in the launch or early post-marketing stages.

Emerging: a technology that has not yet been adopted in a health care system. Emerging pharmaceuticals are usually in the Phase II or III clinical trial or pre-launch stage. Emerging medical devices are at the pre-marketing stage, or are within six months of being marketed, or have already been marketed, but are only in use in a few centres. This may also include a new indication or use for an existing technology.

Meta-Analysis: a statistical method that consists of systematically combining results from different studies to obtain a quantitative estimate of the overall effect of a particular intervention or variable.

Reference Check: a review of all the sources cited in the document ensuring that they are accurate and follow Citing Medicine bibliographic standards.

Stakeholders: organizations, institutions or individuals who have a strong and vested interest in specific CADTH projects and their outcomes. Stakeholders may include:

- Federal / Provincial / Territorial Ministries of Health;
- Hospitals and Health Institutions;
- Health Regions;
- Patients, Consumers and Caregivers;
- Health Professionals; and
- Industry.