Cortellis CMC Intelligence

市販後変更申請対応

発効予定ガイドラインやドラフト版文書、意見募集中のガイドライン案情報をアップデートする

例：中国におけるバイオロジクス製品の市販後変更申請または臨床試験アメンドメントに関連するガイドライン、ドラフト版の文書、意見募集中のガイドライン案を確認する

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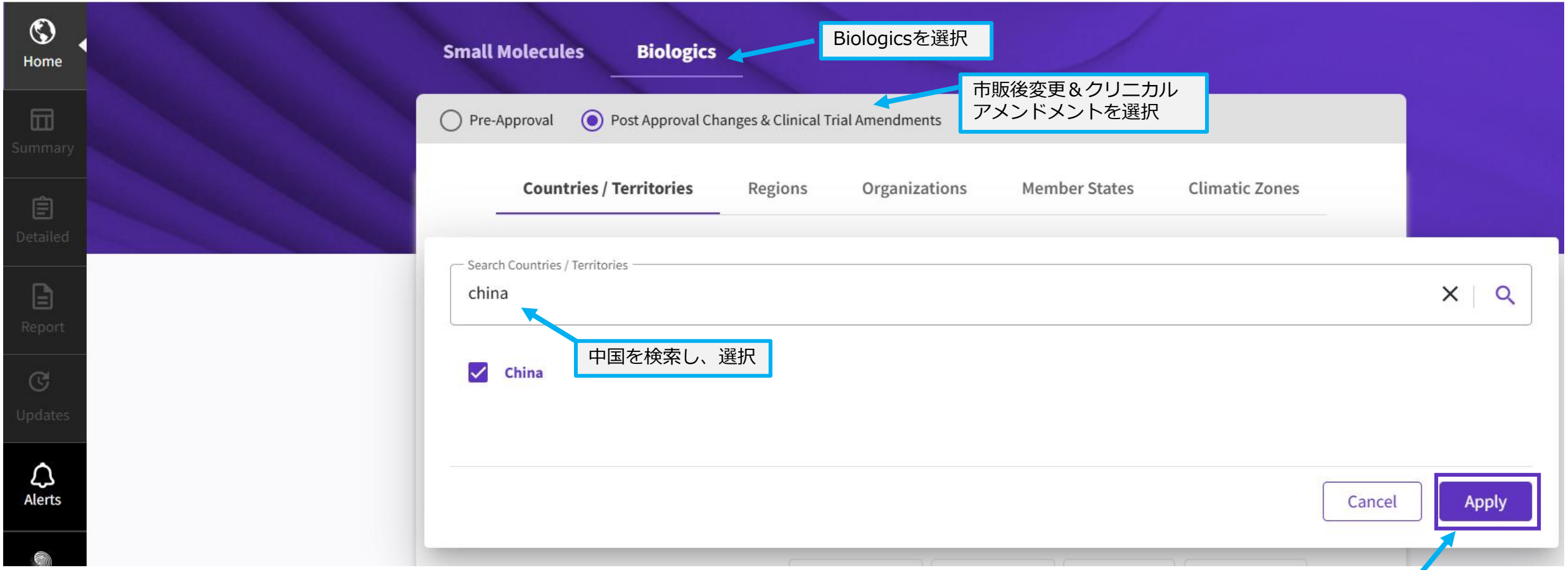

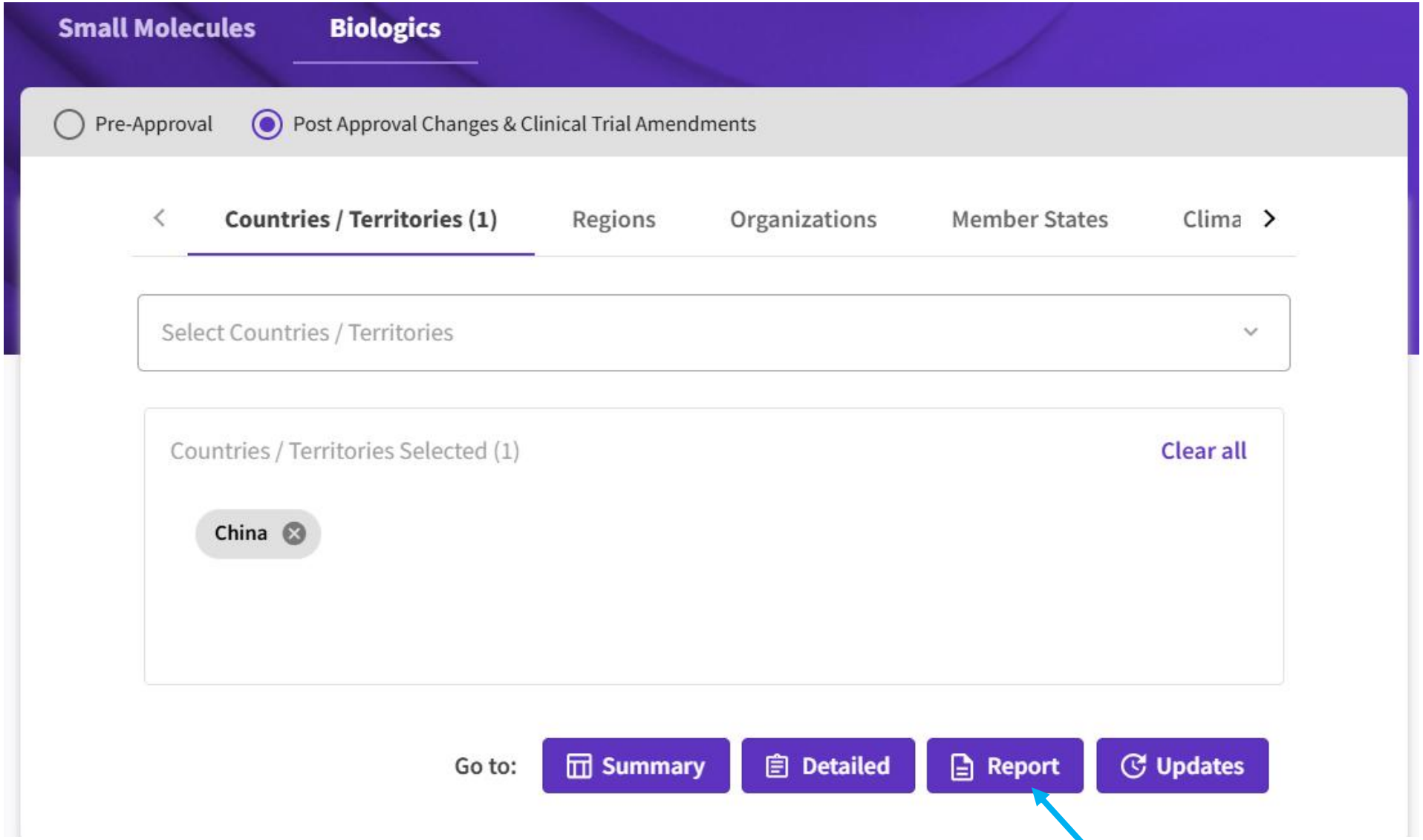
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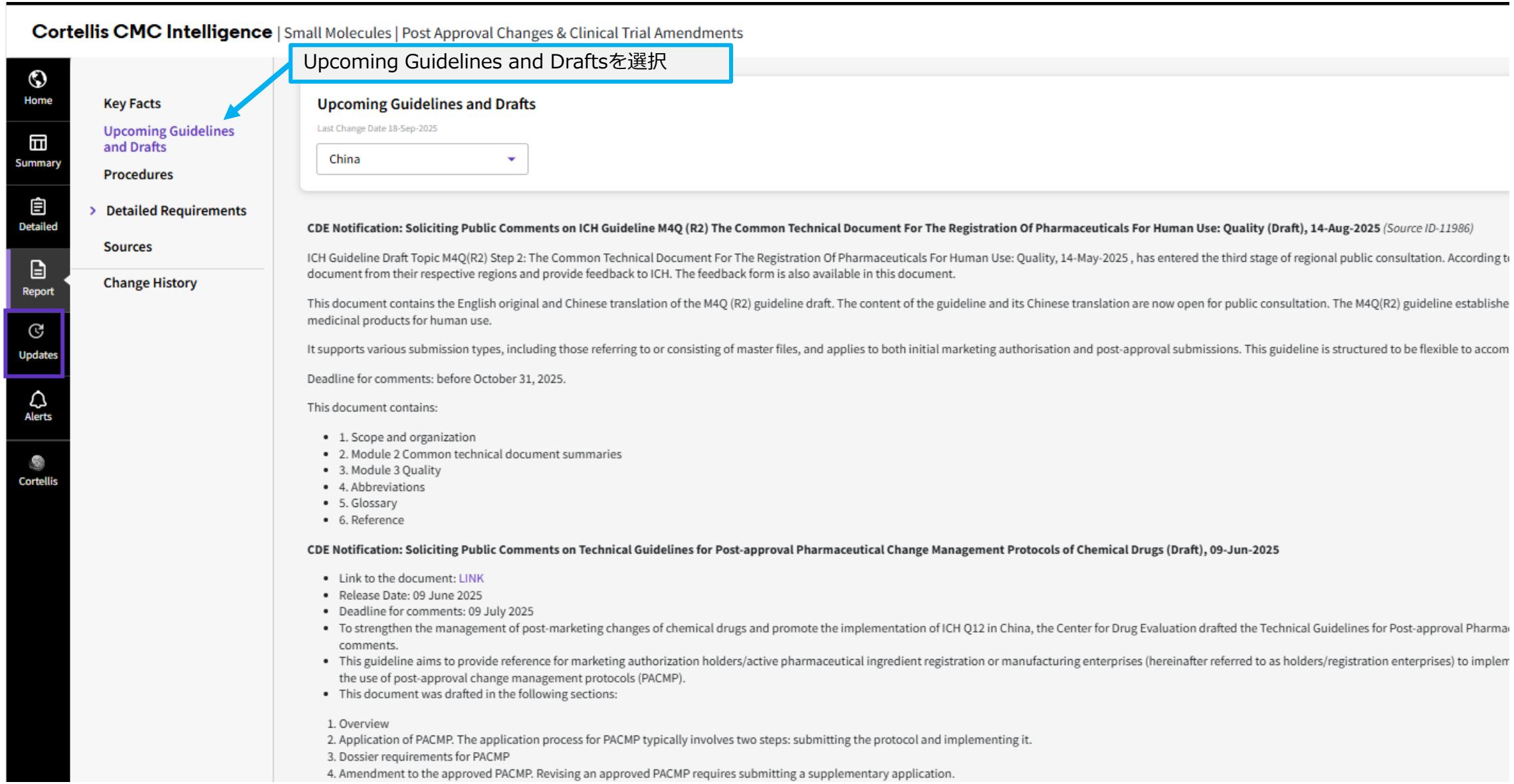
Cortellis CMC Intelligence | Small Molecules | Post Approval Changes & Clinical Trial Amendments
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China
CDE Notification: Soliciting Public Comments on ICH Guideline M4Q (R2) The Common Technical Document For The Registration Of Pharmaceuticals For Human Use: Quality (Draft), 14-Aug-2025 (Source ID-11986)
ICH Guideline Draft Topic M4Q(R2) Step 2: The Common Technical Document For The Registration Of Pharmaceuticals For Human Use: Quality, 14-May-2025 , has entered the third stage of regional public consultation. According t
document from their respective regions and provide feedback to ICH. The feedback form is also available in this document.
This document contains the English original and Chinese translation of the M4Q (R2) guideline draft. The content of the guideline and its Chinese translation are now open for public consultation. The M4Q(R2) guideline establishe
medicinal products for human use.
It supports various submission types, including those referring to or consisting of master files, and applies to both initial marketing authorisation and post-approval submissions. This guideline is structured to be flexible to accom
Deadline for comments: before October 31, 2025.
This document contains:
1. Scope and organization
2. Module 2 Common technical document summaries
3. Module 3 Quality
4. Abbreviations
5. Glossary
6. Reference
CDE Notification: Soliciting Public Comments on Technical Guidelines for Post-approval Pharmaceutical Change Management Protocols of Chemical Drugs (Draft), 09-Jun-2025
Link to the document: LINK
Release Date: 09 June 2025
Deadline for comments: 09 July 2025
To strengthen the management of post-marketing changes of chemical drugs and promote the implementation of ICH Q12 in China, the Center for Drug Evaluation drafted the Technical Guidelines for Post-approval Pharma
comments.
This guideline aims to provide reference for marketing authorization holders/active pharmaceutical ingredient registration or manufacturing enterprises (hereinafter referred to as holders/registration enterprises) to implem
the use of post-approval change management protocols (PACMP).
This document was drafted in the following sections:
1. Overview
2. Application of PACMP. The application process for PACMP typically involves two steps: submitting the protocol and implementing it.
3. Dossier requirements for PACMP
4. Amendment to the approved PACMP. Revising an approved PACMP requires submitting a supplementary application.