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Access to Regulatory Authorities in Vietnam

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Key Departments of Minister of Health-Vietnam

Drug Administration

- Manage/Approve Marketing Authorization of Drugs/Biologics/Vaccines/Cosmetics
- Assess GMP (Pharmaceuticals and Vaccines)
- Release the Business License in Pharmaceuticals/Vaccines/Biologics

Medical Devices Administration

- Manage/Approve Marketing Authorization of Medical Devices
- Manage/Approve Import License for Medical Devices

Administration of Science Technology and Training

- Manage/Approve Clinical Trials
- Perform GCP Inspection for Clinical Trials in Vietnam

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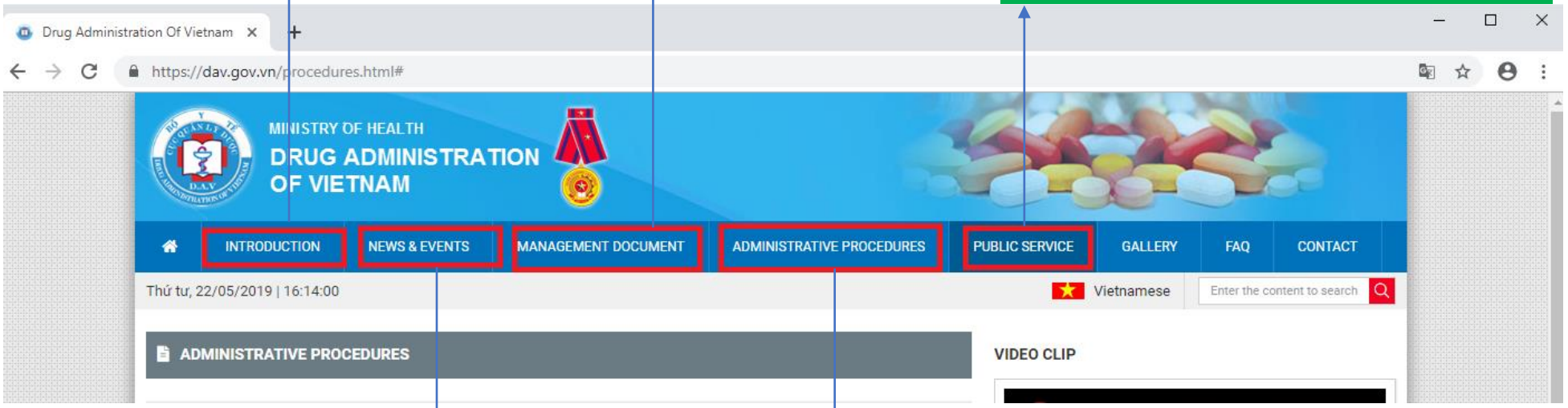
Introduction to Drug Administration- Vietnam

http://dav.gov.vn

General introduction to Drug Administration of Vietnam (DAV)
- Function & Assignment
- Organizational Structure
- Incumbent Leader
- Department Information

Management Document
- Legal Normative Document
- Etc.

Public Service for
- Receipt of cosmetic publishing
- Drug registration
- Receive drug information and confirm drug advertising content
- To declare and re-declare drug prices
- To receive import dossiers and procedures for import of raw materials and packages



Updated News and Events on
- Notification on Drugs marketed in Vietnam (warning letters)
- Direct Management
- ISO administrative reform (SOPs for administrative process at DAV)
- Information processing infringe

Administrative Procedures on
- First Application and Renewal for Pharmaceutical Products (Generic or New Drug/Biologics/Biosimilars)
- Application for Cosmetics Publishing Number
- Approval of Advertising Information on Cosmetics
- Application for Vaccine products manufactured in foreign countries
- Etc.

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Introduction to DAV-Public Service

Transparency of information and management

Online submission

Linked to Customs System

In progress of development

Online databases

Cosmetics published in Vietnam

Pharmaceuticals registered in Vietnam

Advertising content registered in Vietnam

Price declaration of pharmaceutical products registered in Vietnam

In progress of development

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Drug Registration Flow-chart

Generics or NDA
(ACTD Template/Guidelines)

New Drug Application (NDA)
(ICH CTD Template/Guidelines)

Fees for review process
(to submit directly to the bank account of DAV)
NDA: 30,000 yen
Drug with BA/BE: 27,500 yen
Others: 22,500 yen

Review Timeline (1st)
New Drug Application: 6 months
1st Registration of Import Drug: 12 months

Explanation Timeline
Pre-clinical/Clinical Trials: 36 months
Stability Data and others: 12 months

Preparation

Submission (on-line or off-line)

Sufficiency Review — No → Preparation

Yes

Required fees? — No → Drug/Vaccines/Biologics Review Board

Yes

Submitted to DAV? — No → Destruction (Quarterly)

Yes

Drug/Vaccines/Biologics Review Board

- Administration (CPP, GMP etc.)
- Specification/ Stability etc.
- Dosage Form
- Pharmacology
- Pre-Clinical/Clinical Data *NDA

Deficiency? — Yes → 1st or 2nd Notification? — Yes → Preparation

1st or 2nd Notification? — No → Rejection

Deficiency? — No → DAV-Review Board

DAV-Review Board → Marketing Authorization (MA)

0.5 month
3 months

3 months
6 months

1 month
2 months

1.5 months
1 month

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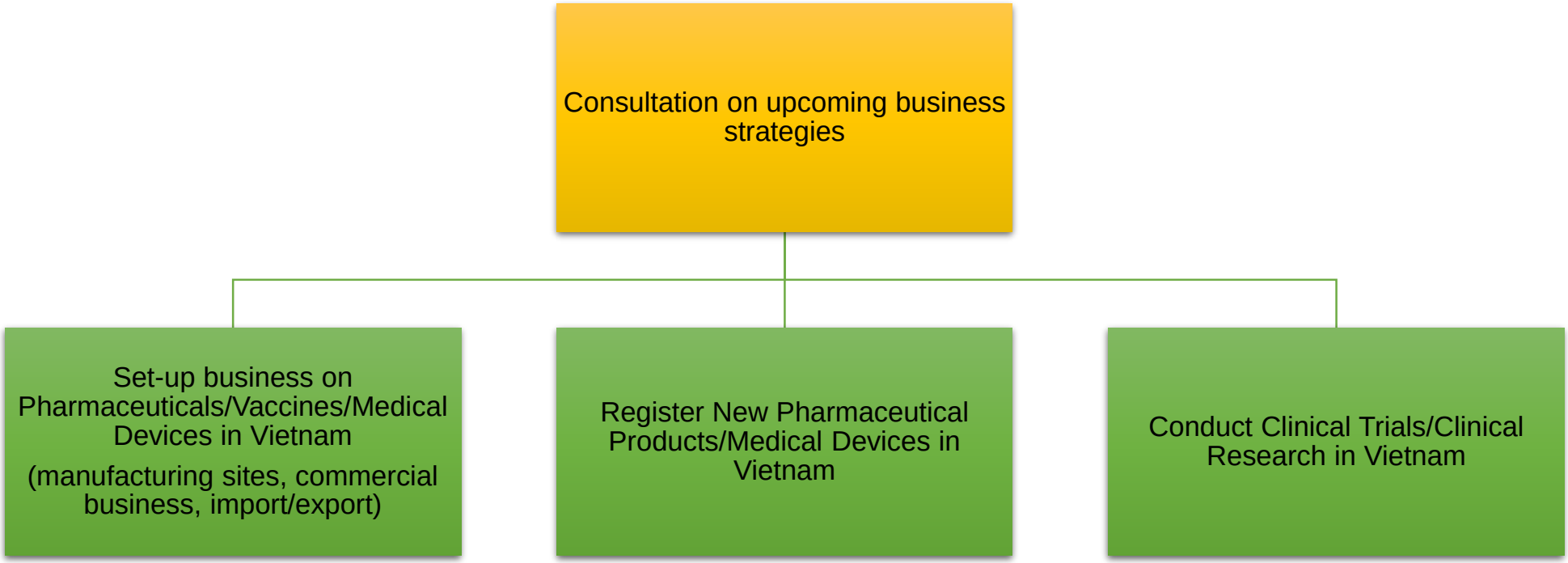
Reference: Circular 32/2018/TT-BYT date 12 Nov 2018

Aspects to Approach Regulatory Authorities- Vietnam



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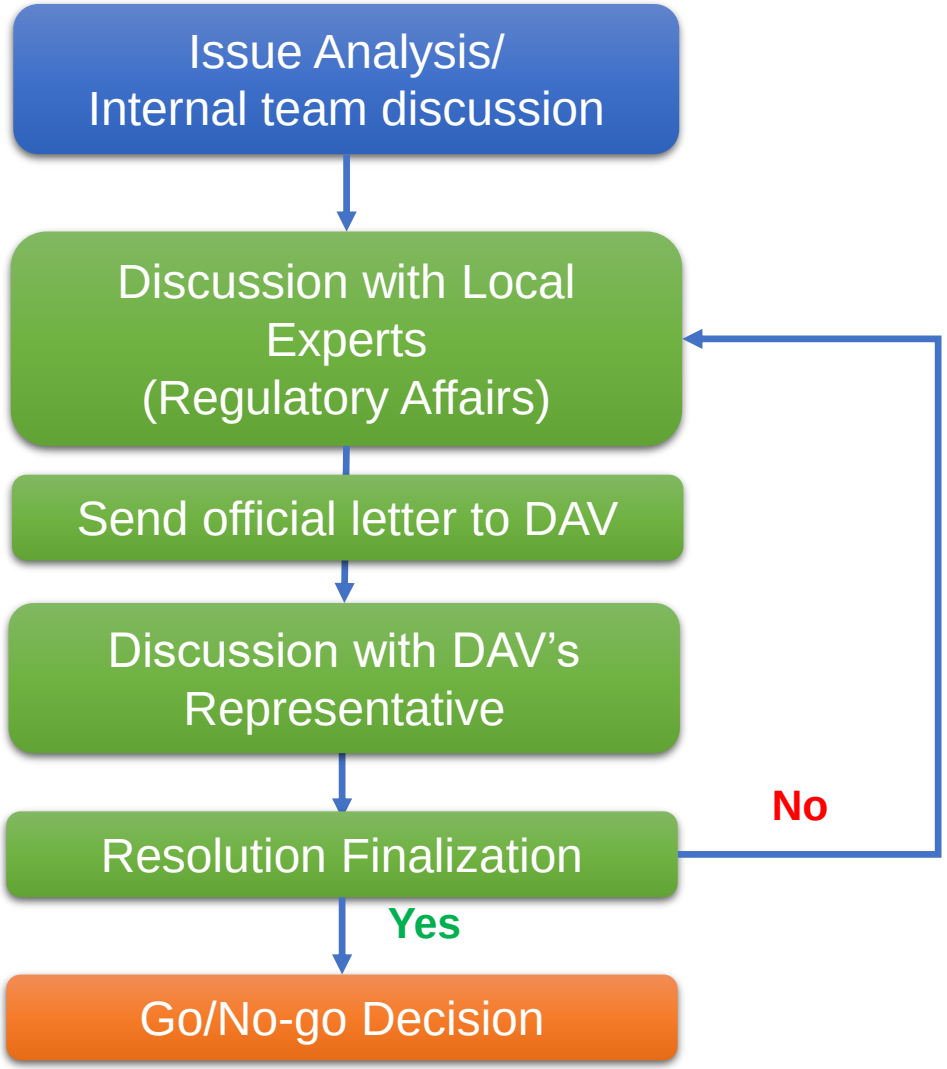
Working with Drug Administration-Vietnam



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Case Scenario

I. A **biosimilar** was marketed in China in 2009 with Marketing Authorization issued for **Generics classification** because there was little guidance available for biosimilars. China FDA issued “Technical Guidelines for R&D and evaluation of Biosimilars(Trail)” in 2015.

II. The biological company intended to market the product in Vietnam. The DAV adapts the knowledge from **referencing regulatory authorities (WHO, US FDA, EMA, MHRA and PMDA**) to consider that Biosimilars need Clinical Trials to assess safety and efficacy comparing to its referencing biologics in 2018.

III. The company conducted pre-clinical studies and **PK studies** in Chinese population. They also collected systematic **pharmacovigilance data to support** the benefits out-weight of risks for **labeled indications**.

IV. They found the Guidance of US FDA on **Real-World Data/Evidence (RWD/RWE) (draft Guidance in May 2019)** used for evaluating. However, they did not find any guidance on the acceptability of DAV on **foreign** RWD/RWE.

V. The company would expect to have a consultation on the opinion of DAV to prove the **effectiveness and safety** of the biosimilar based on **RWD/RWE (Pharmacovigilance data-Retrospective efficacy/safety data)** and/or **bridging studies-ICH E5** to re-confirm dose regimes.

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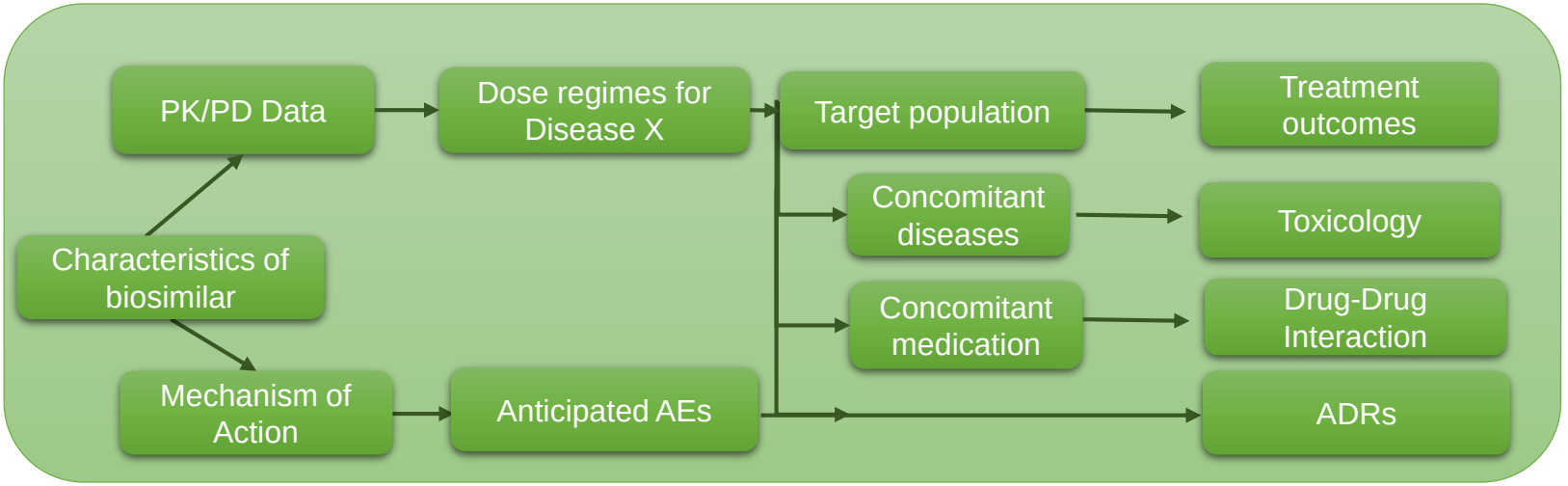
Case Scenario-Scientific Concerns

Established knowledge/understanding in Chinese population based on Real-World Evidence



Knowledge/understandings in Vietnamese population to be established

- Are Pharmacokinetics data similar to Chinese population?
- Are there any clinical immunogenicity issues in Vietnamese population compared to Chinese population?
- Dose regimes for Disease X: Are the doses in Chinese population exponentially applied for Vietnamese population?
- Is the target population in Vietnam similar to Chinese population (demographics, concomitant diseases, concomitant medication)?
- Is the biosimilar similar to biologics in Vietnamese population?
- Are there any concerns on SAEs investigated in large scale studies in Vietnamese population?

Abbreviation
PK: Pharmacokinetics
AE: Adverse Event
SAE: Serious Adverse Event
PD: Pharmacodynamics
ADR: Adverse Drug Reaction

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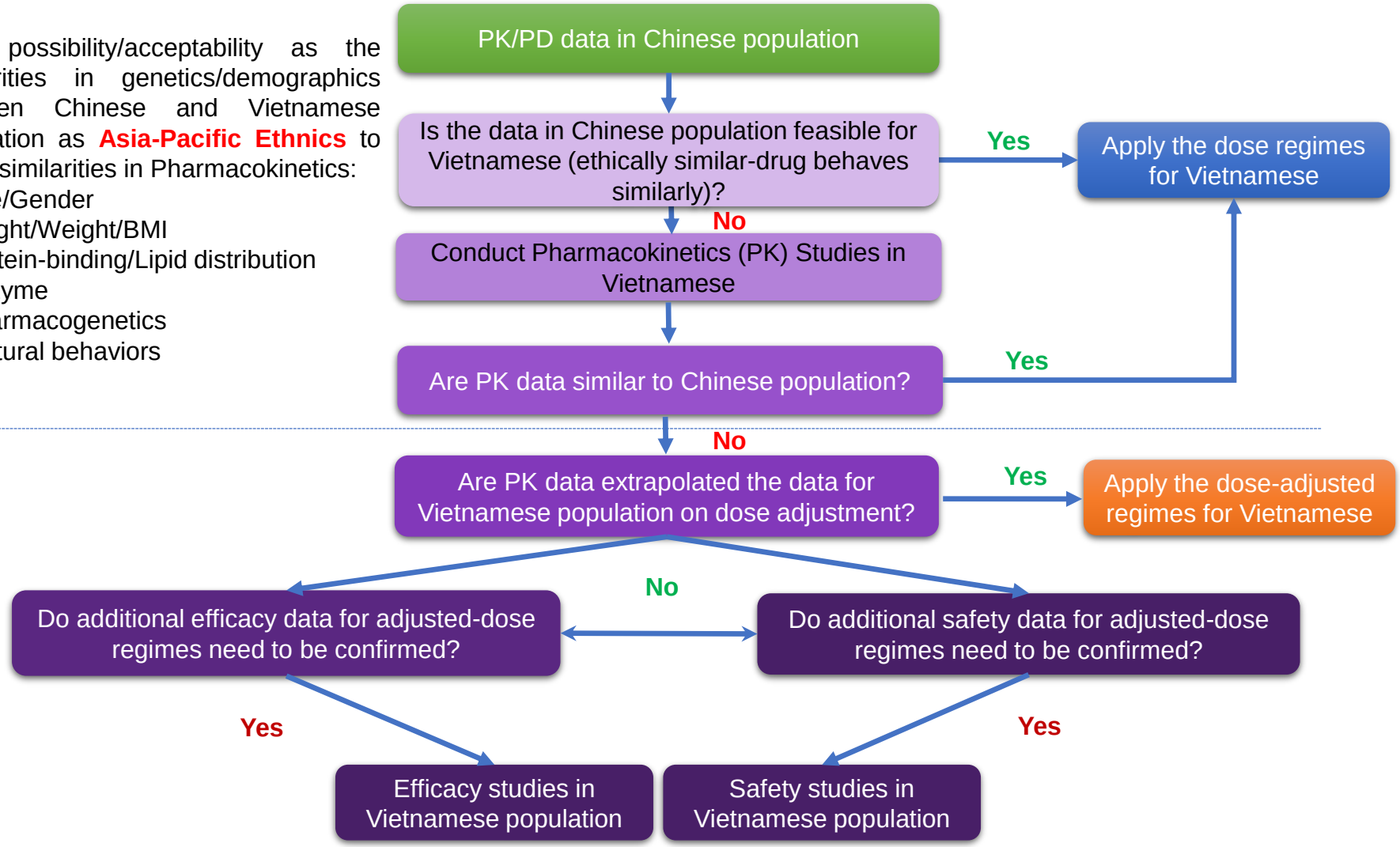
Case Scenario-ICH E5 Bridging Studies

High possibility/acceptability as the similarities in genetics/demographics between Chinese and Vietnamese population as **Asia-Pacific Ethnics** to prove similarities in Pharmacokinetics:

- Age/Gender
- Height/Weight/BMI
- Protein-binding/Lipid distribution
- Enzyme
- Pharmacogenetics
- Cultural behaviors
- Etc.



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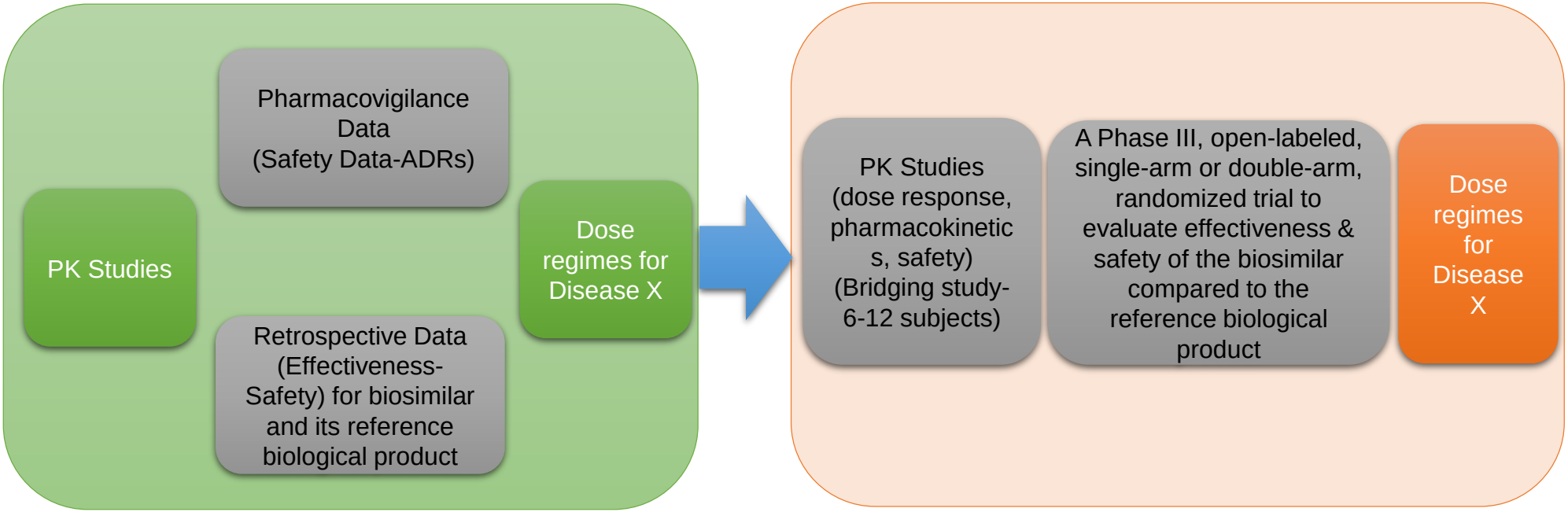
Case Scenario-Planned Study Designs

Establish effectiveness-safety data in Chinese population for justification for the labelled indications based on Real-World Evidence

Establish bridging studies and/or effectiveness-safety data in Vietnamese population to propose labelled indications



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Key Take-Home Messages

- The Vietnam government, including MOH, are taking seriously the improvement in their Public Services by applying new technology.
- The Minister of Health, particularly DAV, harmonizes the regulatory system according to ASEAN CTD and relies on referencing Regulatory Authorities (ICH regions including Japan) and World Health Organization for its guidance.
- Be well-prepared and knowledgeable before approaching public organization with insight guidance from local experts.

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Thank you very much for your attention!

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