Protocol of Horizontal Scanning for Innovative Medicines

Introduction

Hong Kong's healthcare landscape is marked by a complex interplay between patient needs, regulatory frameworks, and the availability of innovative therapies. Despite significant advancements in medical science, there remain substantial unmet needs in specific therapeutic areas, particularly for diseases that lack effective treatment options.

Globally, many innovative drugs being actively investigated in clinical trial settings or they have already been approved by major registries such as the US Food and Drug Administration (FDA)(1), European Medicines Agency (EMA)(2), and National Medical Products Administration (NMPA)(3) in Mainland China. These breakthrough therapies often significantly improve patient outcomes. Some of these drugs may not yet be approved locally, or approved as self-financed drugs only.

Objectives

This project aims to conduct a horizontal scanning of innovative medicines for treatment-resistant depression, prostate cancer, and inflammatory bowel disease, including ulcerative colitis and Crohn's disease. The goal is to assist policy makers with the decision to review and update the drug formulary list, ultimately improving patient survival rates and quality of life.

Methods

The process was displayed in Figure 1.

Stage 1 General searching for the medical treatments for the specific therapeutic area were first conducted in ScanMedicine(4), a website with comprehensive trial records. With specific and comprehensive search terms, trial records from 20 years prior to the search date up to the search date were included, (i.e., for treatment-resistant depression, prostate cancer, and inflammatory bowel disease, searching period was sent from January 1st, 2003 to the exact search date in 2023). Clinical trials in phases 2, 3, and 4, with all statuses (excluding terminated and withdrawn), registered in any country will be included. According to the inclusion criteria and exclusion criteria of the trial for the subject eligibility as well as objective of the trials, relevant medicines were manually extracted from the records that met these criteria.

Stage 2 Identify innovative medicine. Innovative medicines were identified under the following conditions: 1) the medicine was in Phase 2 or Phase 3 trial stage and not yet approved for the specific therapeutic area by the drug regulatory agency; or 2) the medicine was approved for the specific therapeutic area by at least one of FDA, EMA, NMPA, or Hong Kong Drug Office(5), but not yet included in Hong Kong public formulary(6) or enlisted as self-financed items only.

Stage 3 Verify innovative medicines list. The list of innovative medicines will be confirmed by clinical collaborators including specialist in the therapeutic areas, two clinical pharmacists and also industry partners Hong Kong Association of the Pharmaceutical Industry.

Outputs

1. Information of innovative medicines

Using confirmed lists of innovative medicines, we gathered detailed information to introduce these medicines to policymakers, researchers, and the general public. All information was verified by professional scholars.

2. Pooled evidence

We identified several medicines that lacked pooled evidence. To address this, we conducted and will continue to conduct systematic reviews and meta-analyses to demonstrate their efficacy and safety in treating specific therapeutic areas. This will provide valuable references for policymakers, researchers, and the general public.

References

1. U.S. Food & Drug Administration; [cited 2024 Sept. 11]. Available from: https://www.fda.gov/.

2. European Medicines Agency; [cited 2024 Sept. 11]. Available from: https://www.ema.europa.eu/en/homepage.

3. National Medical Products Administration; [cited 2024 Sept. 11]. Available from: https://www.nmpa.gov.cn/.

4. ScanMedicine; [cited 2024 Sept. 11]. Available from: https://scanmedicine.com/.

5. Drug Office; [cited 2024 Sept. 11]. Available from: https://www.drugoffice.gov.hk/eps/do/en/level.html.

6. HA Drug Formulary Management: HA Drug Formulary; [cited 2024 Sept. 11]. Available from: https://www.ha.org.hk/hadf/en-us/Updated-HA-Drug-Formulary/Drug-Formulary.html.

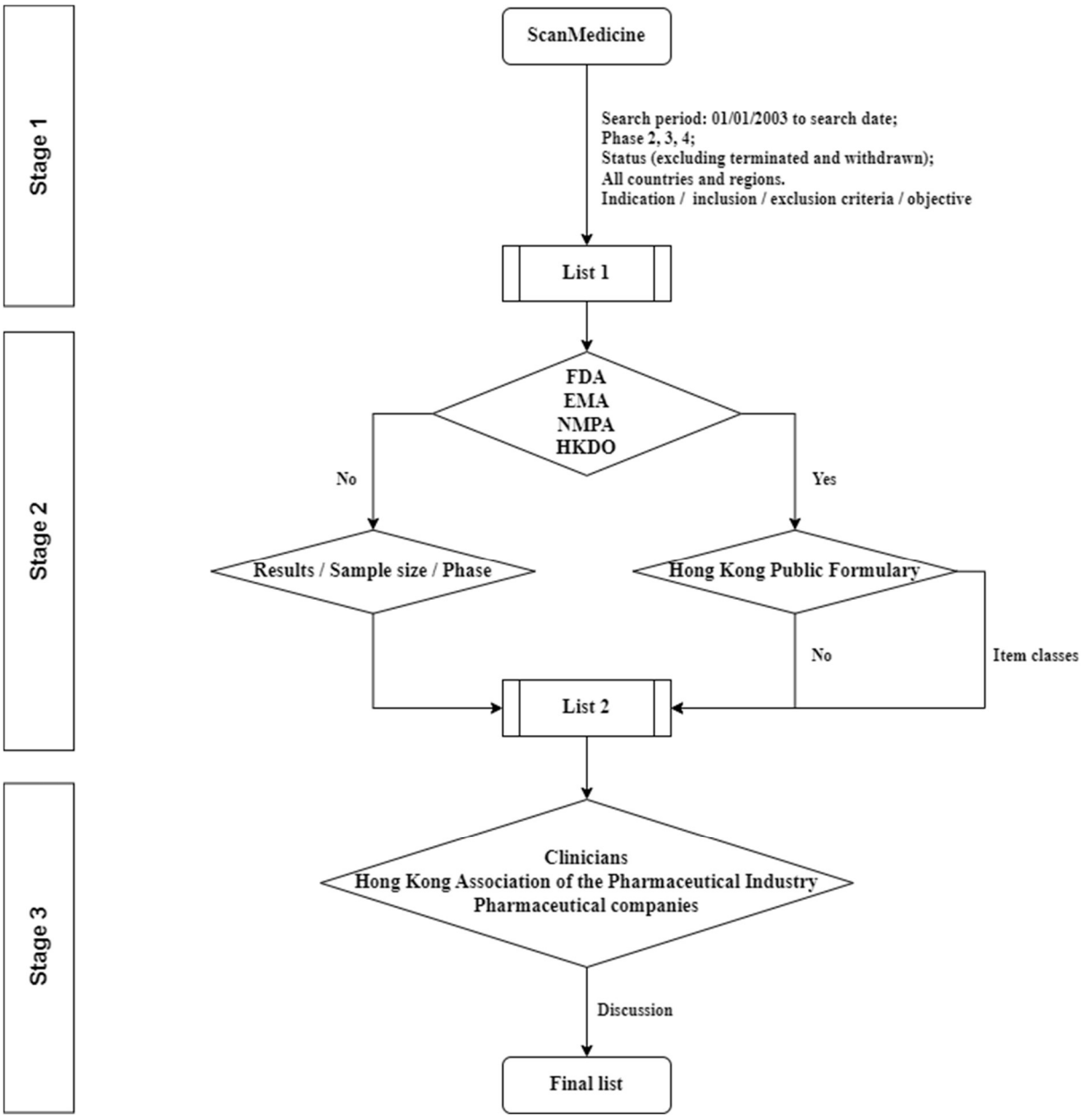

Figure 1. Flowchart of innovative medicine identification

FDA: US Food and Drug Administration
EMA: European Medicines Agency
NMPA: National Medical Products Administration
HKDO: Hong Kong Drug Office
Item classes: general, specific, self-financed items