

China Health Related Outcomes Measures (CHROME)

Feng Xie
Professor of Health Economics
McMaster University



Disclosures

- Member of the EuroQol Group, a nonprofit research foundation and the developer of the EQ-5D instruments
- Elected member and Vice Chair of the EuroQol's Executive Committee.
- Co-lead of the CHROME project
- I have received research funds from the EuroQol Research Foundation.
- A faculty in the department of Clinical Epidemiology and Biostatistics where Health Utility Index (HUI) was originally developed.

CHROME Team

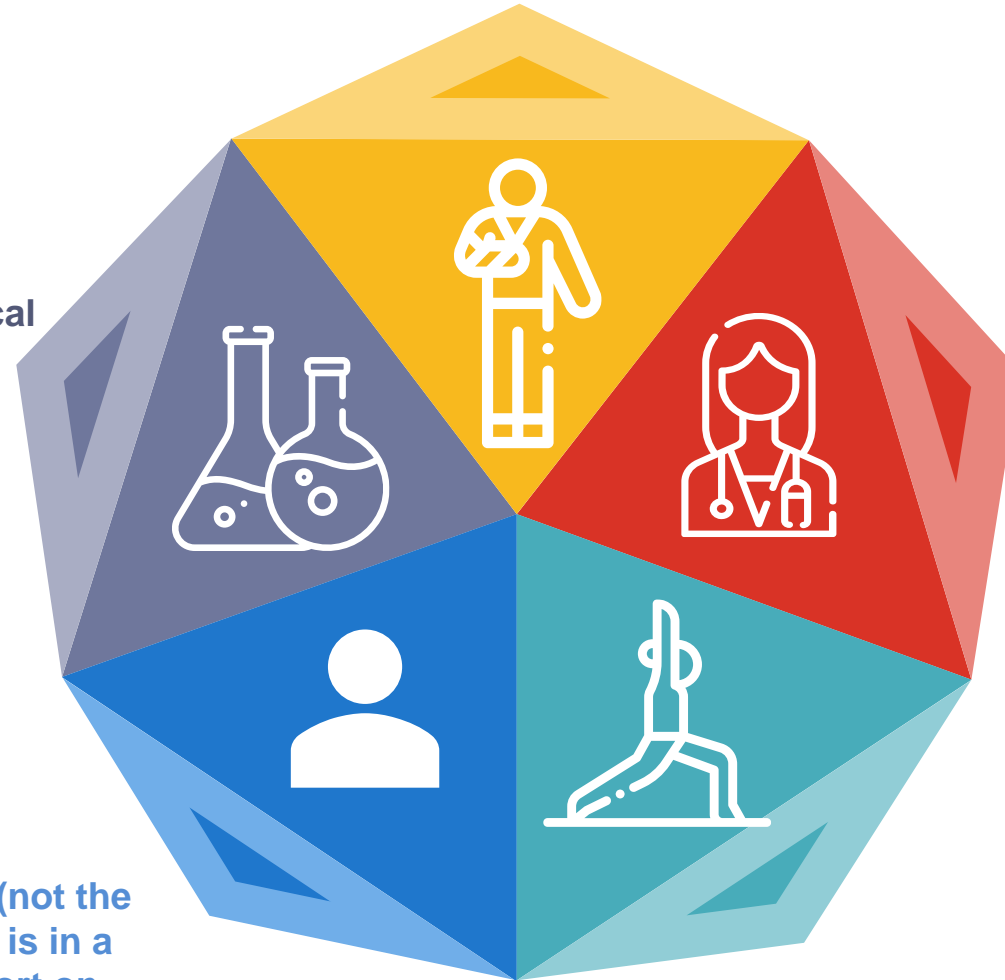


Outline

- **Introduction to CHROME (Prof. Feng Xie)**
- **Development of Generic Module of CHROME (Dr. Shitong Xie)**
- **Development of Cardiovascular Module of CHROME (Dr. Xue Li)**
- **Q&A**

Patient-reported outcomes (PROs)

Directly from patients about their health



Biomarkers

Physiologic, pathologic, or anatomical characteristics of a patient

Clinician-reported outcomes

Clinical judgement or interpretation of observable sign, behaviours, or other physical or mental manifestations thought to be related to a disease

Observer-reported outcomes

Patient health observed by someone (not the patient or a health professional) who is in a position to regularly observe and report on patient's health


Performance outcomes

Measurements based on a task performed by a patient as instructed by a health care professional

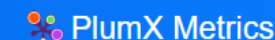
FULL LENGTH ARTICLE | VOLUME 70, ISSUE 1, P60-64, JULY 01, 1992

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Comparison of patient-reported outcomes after elective coronary artery bypass grafting in patients aged \geq and <65 years

[Edward Guadagnoli, PhD](#)  • [John Z. Ayanian, MD, MPP](#) • [Paul D. Cleary, PhD](#)

DOI: [https://doi.org/10.1016/0002-9149\(92\)91390-P](https://doi.org/10.1016/0002-9149(92)91390-P)

[Abstract](#)

This paper is only available as a PDF. To read, Please [Download here](#).

[References](#)

Abstract

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Older patients represent a growing proportion of patients undergoing coronary artery bypass grafting (CABG). Although functional benefits after CABG have been demonstrated, most assessments of outcomes have involved patients aged <65 years. Therefore, little is known concerning the impact of CABG on older patients compared with that on younger ones. A number of postsurgical (6 months) health-related quality-of-life outcomes (e.g., symptoms, cardiac functional class, instrumental activities of daily living, and emotional and social functioning) reported by patients aged <65 ($n = 169$) and ≥ 65 ($n = 99$) years who underwent elective CABG at 4 major teaching hospitals in Massachusetts and California were compared. The proportion of patients reporting cardiac-related symptoms after surgery did not vary by age, and quality-of-life outcome scores of younger and older patients did not differ even after adjustment for clinical and demographic characteristics. The exception to this was mental health status, an outcome for which older patients reported better

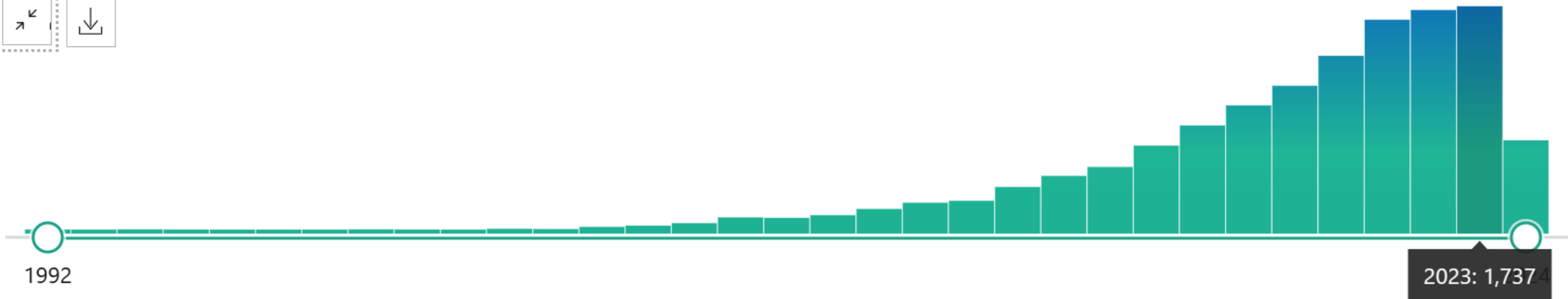
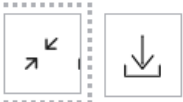


Searching “patient-reported outcomes” by title

RESULTS BY YEAR

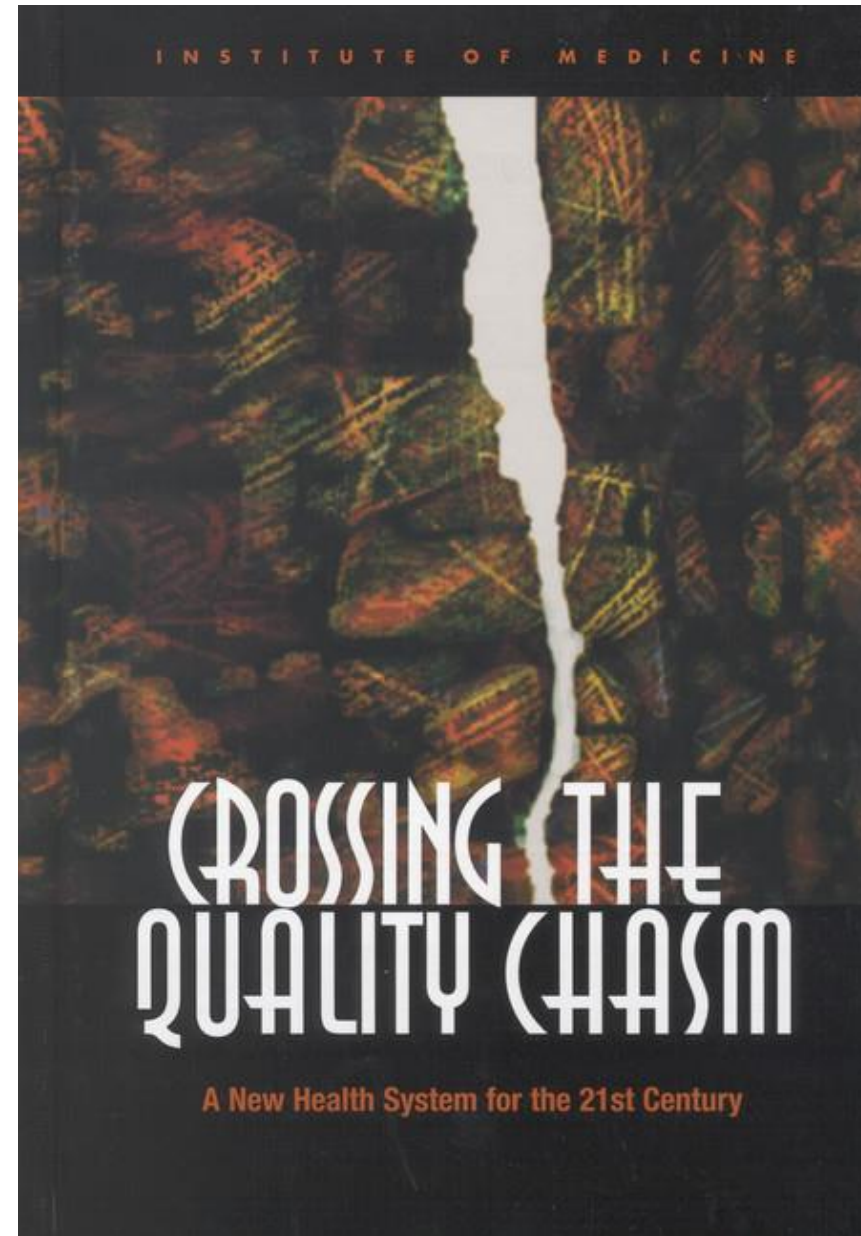
10,862 results

Page 1 of 1,087



**“Providing care
that is respectful
of, and
responsive to,
individual patient
preferences,
needs and values,
and ensuring that
patient values
guide all clinical
decisions.”**

Institute of Medicine
2001





Patient-Centered Outcomes Research Institute

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A photograph of a medical examination. A male doctor with grey hair, wearing a light blue button-down shirt, is leaning over a young boy sitting on an examination table. The doctor is using a stethoscope to listen to the boy's chest. A woman with long dark hair, wearing a white t-shirt, is sitting next to the boy, holding his hand and looking at the doctor. The background shows a clinical setting with a white cabinet and a blue curtain.

Improving Outcomes Important to Patients

PCORI funds studies that can help patients and those who care for them make better-informed healthcare choices.



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Strategy for Patient-Oriented Research

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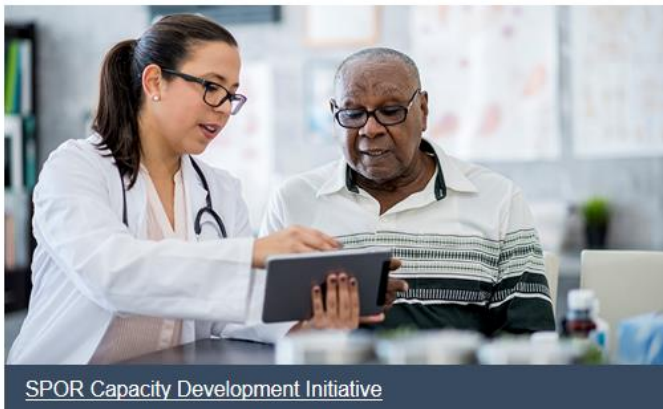
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Strategy for Patient-Oriented Research



SPOR Capacity Development Initiative



Item
3 of 3



Pause

Strategy for Patient-Oriented Research

SPOR

Putting Patients First



Patient-oriented research is about engaging patients, their caregivers, and families as partners in the research process. This engagement helps to ensure that studies focus on patient-identified priorities, which ultimately leads to better patient outcomes.

At CIHR, we want to help transform the role of patient from a **passive receptor** of services to a **proactive partner** who helps shape health research and, as a result, health care.

To help make patient-oriented research a reality in Canada, CIHR formed funding partnerships with provinces and territories, philanthropic organizations, academic institutions, and health charities.

The result?

Patient Reported Outcome Measures (PROMs)

Patient Reported Outcome Measures (PROMs) measure health gain in patients undergoing hip replacement, knee replacement and up to September 2017, varicose vein and groin hernia surgery in England, based on responses to questionnaires before and after surgery.

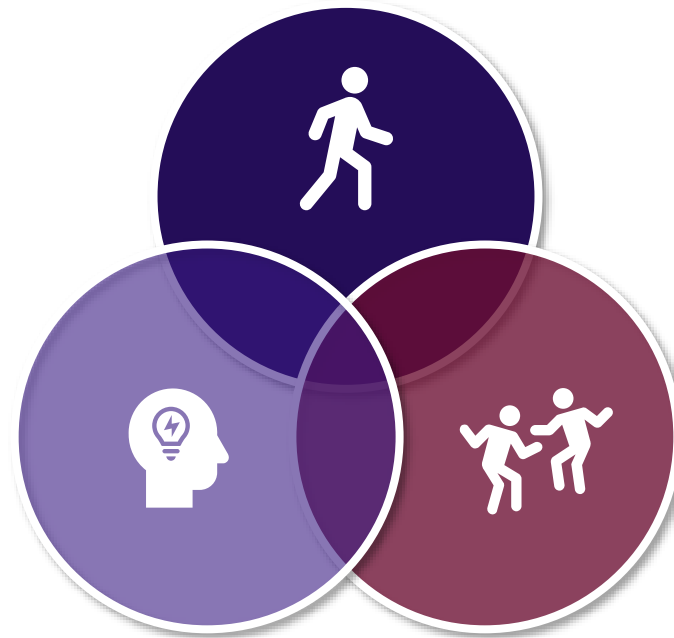


World Health Organization

Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.

Physical health

mobility, physical functioning,
self care



Mental health

anxiety, depression, cognitive
function

Social health

relationship with family and
friends, and social activities

Original Investigation*JAMA Intern Med.* 2018;178(12):1586-1596. doi:10.1001/jamainternmed.2018.4710

December 2018

Evaluating Progression-Free Survival as a Surrogate Outcome for Health-Related Quality of Life in Oncology

A Systematic Review and Quantitative Analysis

Bruno Kovic, PhD¹; Xuejing Jin, PhD^{1,2}; Sean Alexander Kennedy, MD³; Mathieu Hylands, MDCM, MSc⁴; Michał Pędziwiatr, MD, PhD^{5,6}; Akira Kuriyama, MD, MPH⁷; Huda Goma, BPS, BCPS, MSc^{8,9}; Yung Lee, BHSc¹⁰; Morihiro Katsura, MD, MPH¹¹; Masafumi Tada, MD¹²; Brian Y. Hong, MD¹³; Sung Min Cho, BHSc¹⁴; Patrick Ji-ho Hong, BMSc¹⁵; Ashley M. Yu, BHSc, MD¹⁶; Yasmin Sivji, MBBS, MPH¹⁰; Augustin Toma, BSc¹⁰; Li Xie, MSc¹⁷; Ludwig Tsoi, MBChB, MPH¹⁸; Marcin Waligora, PhD¹⁹; Manya Prasad, MD²⁰; Neera Bhatnagar, MLIS, BSc²¹; Lehana Thabane, PhD^{1,22,23,24,25}; Michael Brundage, MD, FRCPC, MSc^{26,27}; Gordon Guyatt, MD, MSc, FRCP, OC^{1,10}; Feng Xie, PhD^{1,28,29}

Key Points

Question How strongly is progression-free survival (PFS) associated with health-related quality of life (HRQoL) in studies of cancer treatments?

Findings This systematic review and quantitative analysis of 52 articles reporting on 38 randomized clinical cancer trials did not find a significant association between PFS and HRQoL.

Meaning These findings raise questions about the assumption that interventions prolonging PFS also improve HRQoL in patients with cancer and suggest that HRQoL should be measured directly and accurately, with adequate follow-up time, in future studies.



Aducanumab (marketed as Aduhelm) Information



Postmarket Drug Safety Information for Patients and Providers

[Index to Drug-Specific
Information](#)

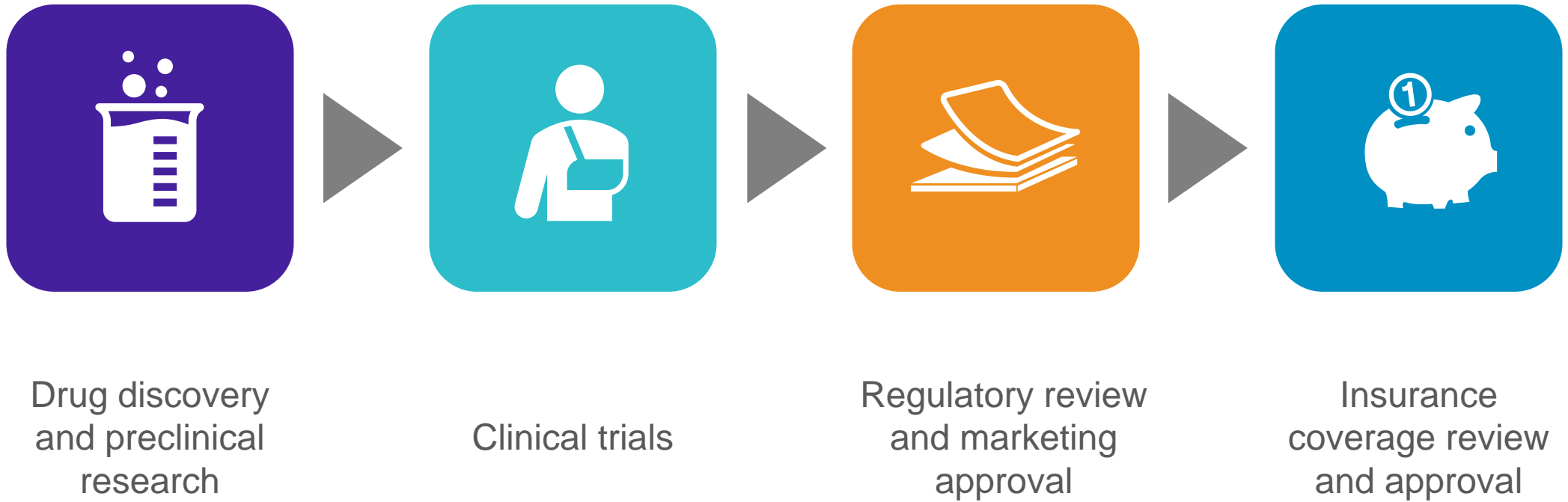
Aduhelm is an amyloid beta-directed antibody indicated to treat Alzheimer’s disease. Aduhelm is approved under the [accelerated approval pathway](#), which provides patients with a serious disease earlier access to drugs when there is an expectation of clinical benefit despite some uncertainty about the clinical benefit.

Accelerated approval is based upon the drug’s effect on a surrogate endpoint — an endpoint that reflects the effect of the drug on an important aspect of the disease — where the drug’s effect on the surrogate endpoint is expected, but not established, to predict clinical benefit. In the case of Aduhelm, the surrogate endpoint is the reduction of amyloid beta plaque. The accelerated approval pathway requires the company to verify clinical benefit in a post-approval trial. If the sponsor cannot verify clinical benefit, FDA may initiate proceedings to withdraw approval of the drug.

Content current as of:
07/08/2021

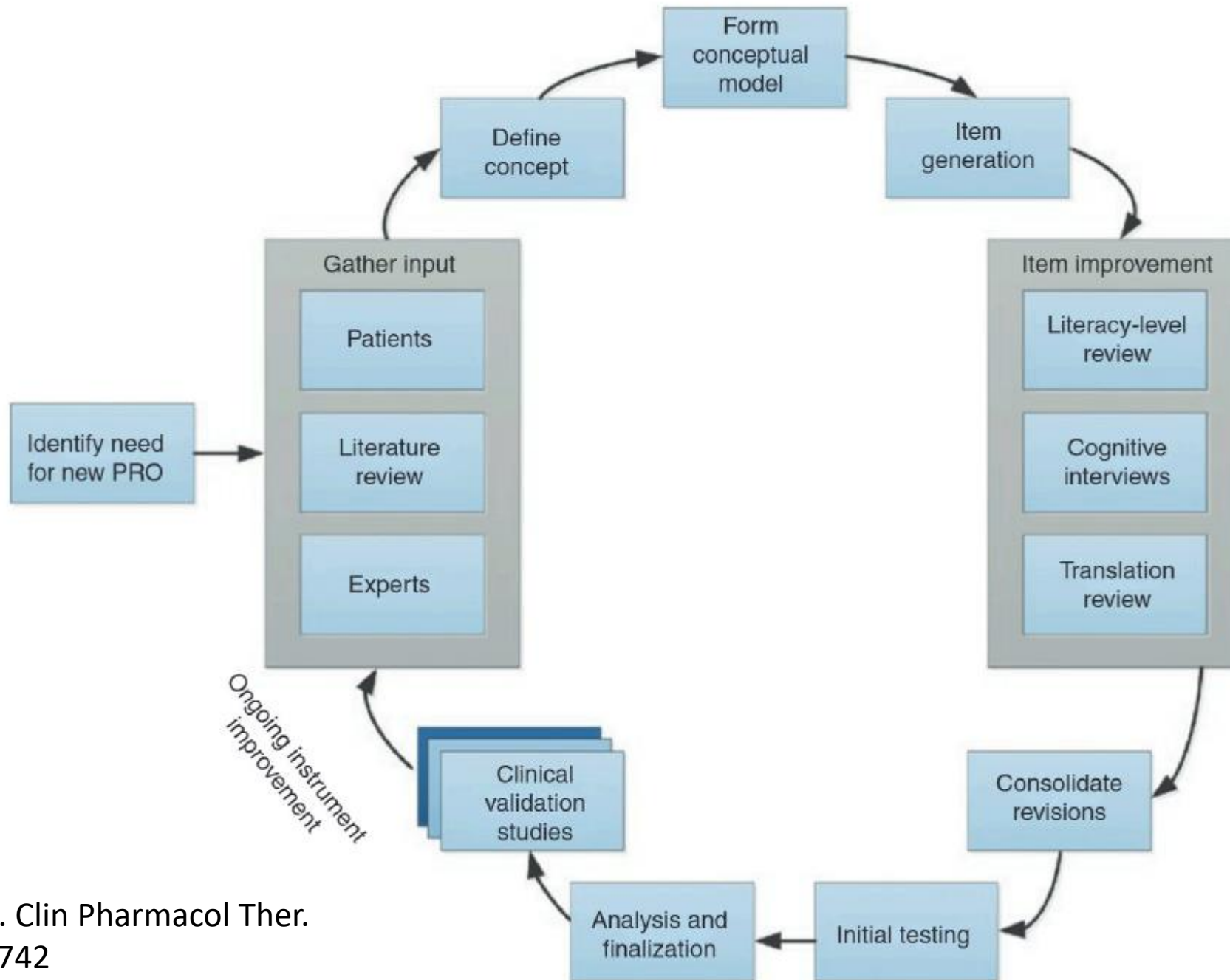
Regulated Product(s)
Drugs

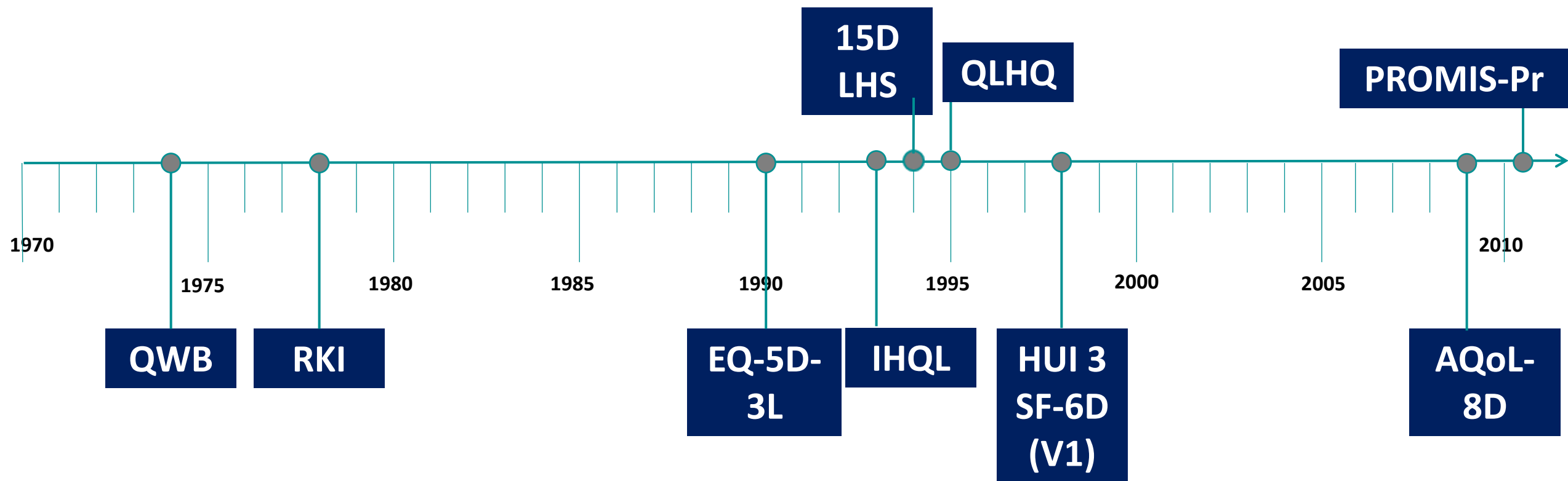
Context



Standardized and validated instruments







Disease-specific preference-based measures

- EORTC-8D
- EORTC QLU-C10D
- FACT-LUI
- Cerebral palsy: CP-6D
- HUG5
- PORPUS
- ...

	Generic	Disease-specific
Pro	<ul style="list-style-type: none"> • Brief and easy to complete • High comparability 	<ul style="list-style-type: none"> • Disease-specific • High sensitivity
Con	<ul style="list-style-type: none"> • Not capturing disease-specific impact • Limited use in clinical setting 	<ul style="list-style-type: none"> • Limited comparability • Respondent burden

Why does China need its own PROMs?

Limitations in existing PROMs

Important health aspects specific to China

Lack of conceptual framework

Silo development for generic and disease-specific measures

Inadequate engagement with target populations

Need to support health technology assessment and coverage policy making

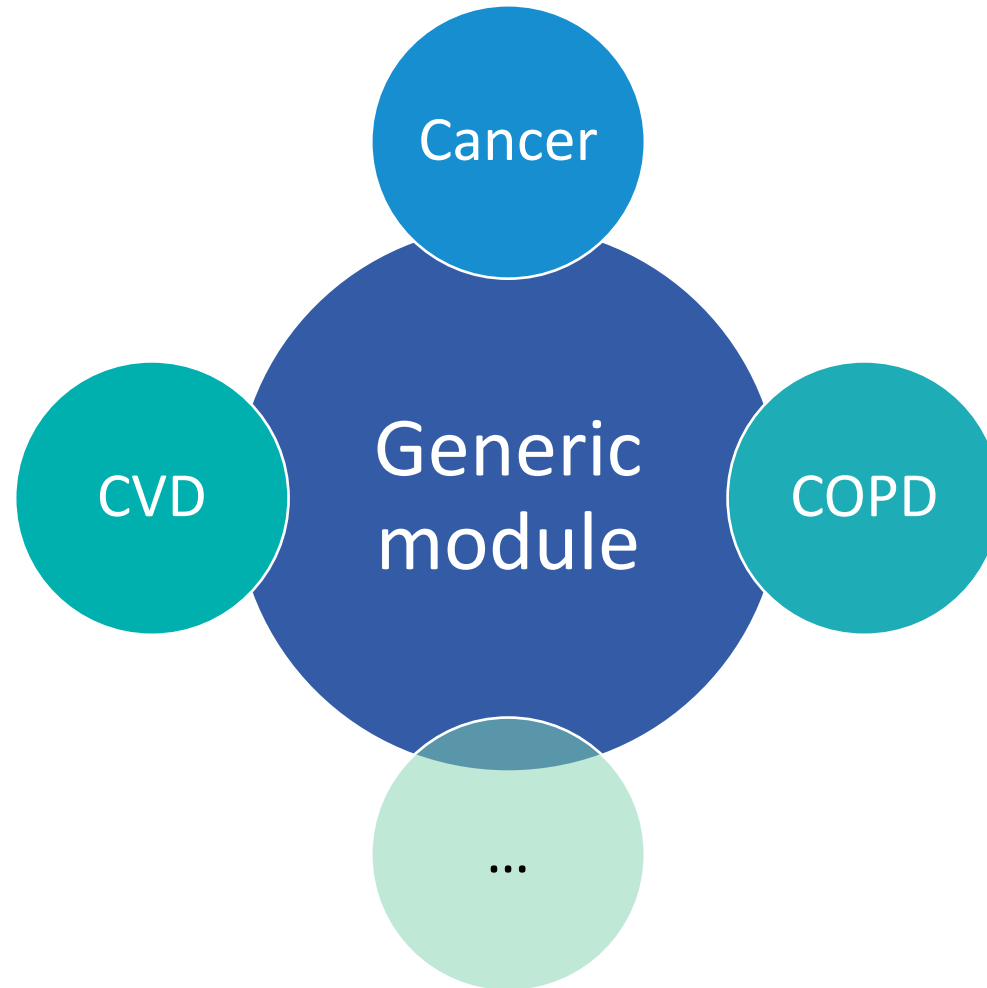


CHROME: a system to measure person/patient reported outcomes for China

- Enabling both generic and disease-specific measurement needs
- Facilitating both clinical and economic evaluations
- Supporting assessments of population-level health
- Informing clinical decision, insurance coverage and broad health policy making




Generic
module



ORIGINAL RESEARCH ARTICLE



China Health Related Outcomes Measures (CHROME): Development of a New Generic Preference-Based Measure for the Chinese Population


Jing Wu^{1,2} · Xiaoning He^{1,2} · Pinan Chen^{1,2} · Shitong Xie^{1,3} · Xue Li^{3,4} · Hao Hu⁵ · Kun Zhao⁶ · Feng Xie^{3,7}  · for the CHROME Study Group

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China Health Related Outcomes Measures (CHROME): development of a descriptive system to support cardiovascular disease specific preference-based measure for the Chinese population

Xue Li^{1,2} · Kun Zhao^{1,3} · Kexin Li⁴ · Wenjun Wang¹ · Siting Feng⁵ · Jing Wu^{6,7} · Xiaoning He^{6,7} · Shitong Xie^{2,6} · Hao Hu⁸ · Jing Fan^{9,10} · Qiang Fu¹² · Feng Xie^{2,11}  · For the CHROME Study Group

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Abstract

Purpose Preference-based measures have been increasingly recommended to measure health outcomes for economic evaluation. However, none of existing cardiovascular disease (CVD)-specific health-related quality of life (HRQoL) instruments are preference-based. This study aimed to develop the descriptive system of preference-based HRQoL instrument for Chinese patients with CVDs under the Initiative of China Health Related Outcomes Measures (CHROME).

Methods Qualitative face-to-face interviews were conducted with Chinese patients with CVDs. Content analysis was employed to generate candidate items for the instrument. Then expert consultation and cognitive debriefing interviews were conducted to guide further selection and revision of the items.

Results We interviewed 127 CVD patients with 67.7% being male and 63.8% living in the urban area. A hierarchical code book comprised of four themes, 20 categories, 62 sub-categories, and 207 codes, was developed. Candidate items were selected based on the criteria set by the Consensus-based Standards for the selection of health Measurement Instruments (COSMIN) methodology and ISPOR PRO guidance. An online survey and meeting with an expert advisory panel ($n = 15$) followed by cognitive debriefing interviews with 20 patients and 13 physicians were conducted to further select and revise the candidate items. The descriptive system of CHROME-CVD consists of 14 items, namely frequency and severity of chest pain,



健康人群问卷
GENERIC PREFERENCE-BASED MEASURE



心血管人群问卷
CARDIOVASCULAR DISEASE SPECIFIC PREFERENCE-BASED MEASURE