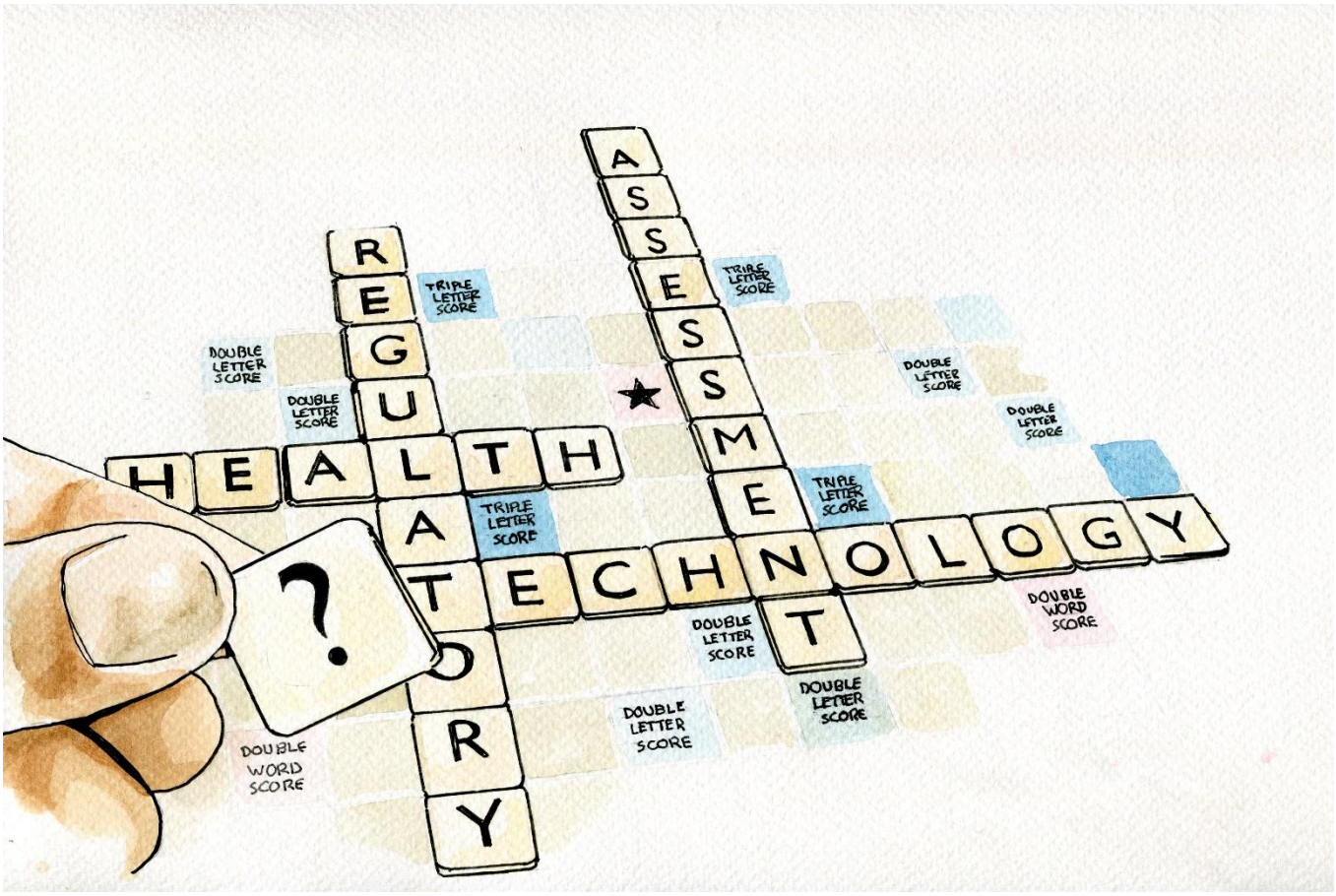

CENTRE FOR INNOVATION IN REGULATORY SCIENCE

HTA INDUSTRY METRICS PROGRAMME 2022

CIRS Centre for Innovation in Regulatory Science

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About CIRS

DRIVING THEMES

METRICS

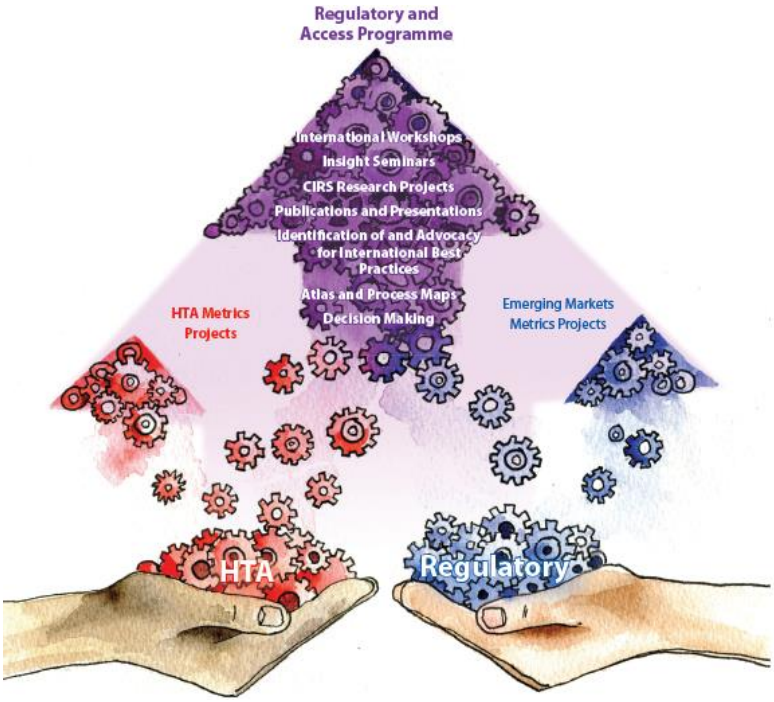
Managing uncertainty and improving predictability

QUALITY OF PROCESS

Improving development and regulatory processes and ultimately, the quality of decision making

ALIGNMENT

Promoting convergence within and across organisations and stakeholders



KEY ACTIVITIES

International Workshops: Meetings for members are convened at which invited participant interactions are optimised to facilitate networking, constructive discussion, recommendations and actions.

CIRS Research Projects: Specialised research and surveys are carried out among leading pharmaceutical companies and regulatory and HTA agencies with expert analyses and interpretation of the findings.

Identification of and Advocacy for International Best Practices: Using findings from our Workshops and research projects CIRS interacts with companies, regulators, HTA agencies and other international organisations to promulgate efficiencies in global medicine development.

Publications and Presentations: Reports are prepared from Workshops and projects. Dissemination of findings and recommendations through the R&D Briefing series, conference presentations, papers in peer-reviewed journals and the CIRS website are key aspects of the CIRS educational communication mission.

CIRS - The Centre for Innovation in Regulatory Science Limited - is a neutral, independently managed UK-based subsidiary company, forming part of Clarivate Analytics (UK) Limited. CIRS' mission is to maintain a leadership role in identifying and applying scientific principles for the purpose of advancing regulatory and HTA policies and processes. CIRS provides an international forum for industry, regulators, HTA and other healthcare stakeholders to meet, debate and develop regulatory and reimbursement policy through the innovative application of regulatory science and to facilitate access to medical products through these activities. This is CIRS' purpose. CIRS is operated solely for the promotion of its purpose. The organisation has its own dedicated management and advisory boards, and its funding is derived from membership dues, related activities, special projects and grants.

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CIRS HTA Industry Metrics Programme 2022

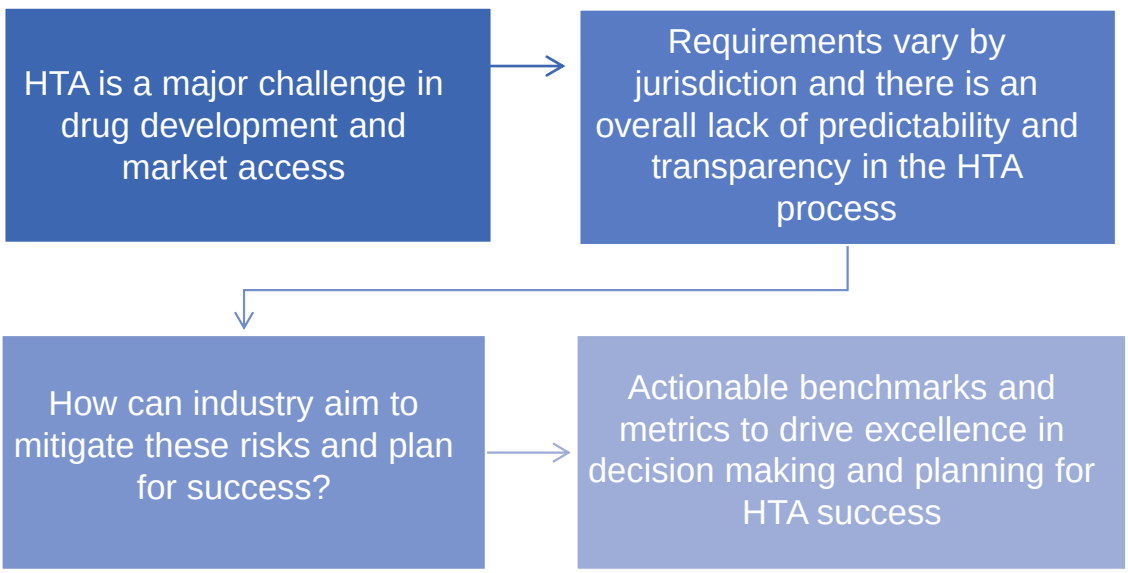
Specific metrics to inform decision making around HTA in development and post-approval stages present a valuable opportunity to improve outcomes and manage risk

BACKGROUND

Health technology assessment (HTA) is now commonplace to evaluate new medicines in order to inform coverage decision making for efficient allocation of healthcare resources. Pharmaceutical companies are under pressure to adjust their drug development and submission strategies to accommodate both regulatory and HTA requirements for commercial success. In addition, the variability in remits of HTA bodies that are utilised in HTA appraisal and coverage decision-making processes in different countries results in a complex and challenging environment. It is therefore important for companies to incorporate a clear understanding of HTA requirements into early strategic planning to mitigate access risks.

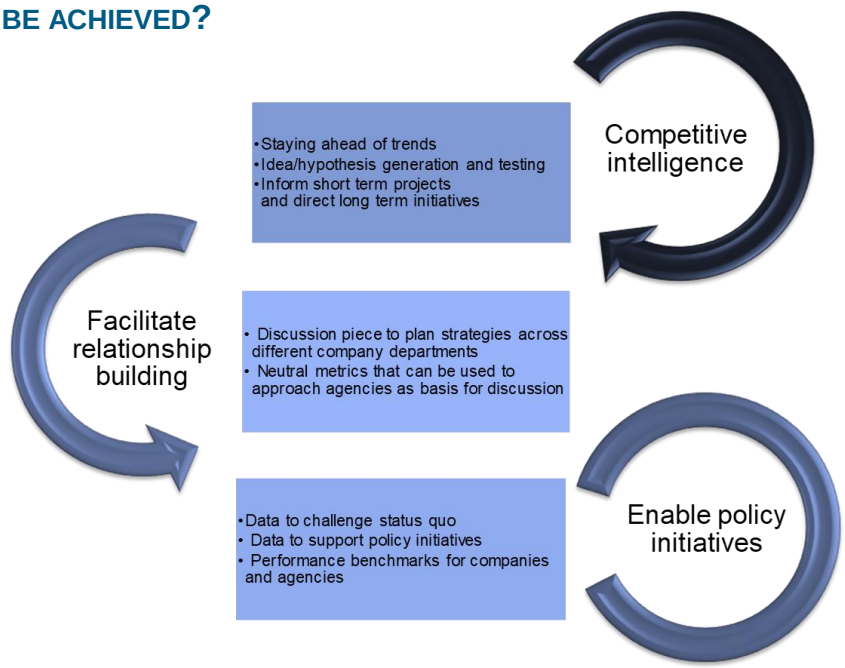
As a result of this, the CIRS HTA Industry Metrics programme was established in 2011 to meet the needs of participant companies for comparative data and information on the evolving HTA environment. The purpose of this project is to give participating companies insight into how HTA requirements are impacting drug development and payer decision making in the context of new medicines being brought to market, to apply combined knowledge and learning and use the results to plan for successful product access. Now in its ninth year, this programme focuses on both the drug development plan and jurisdictional submission strategy for Australia, Canada, England, France, Germany, Italy and Spain.

The annual CIRS HTA Industry Metrics Programme is the first focused effort to benchmark the HTA process by following individual products from development through market access.



CIRS THEME METRICS – MANAGING UNCERTAINTY AND IMPROVING PREDICTABILITY

WHAT CAN BE ACHIEVED?



WHAT IS IT UNIQUE ABOUT HTA METRICS? COLLABORATIVE, CONTINUOUS, COMPARATIVE

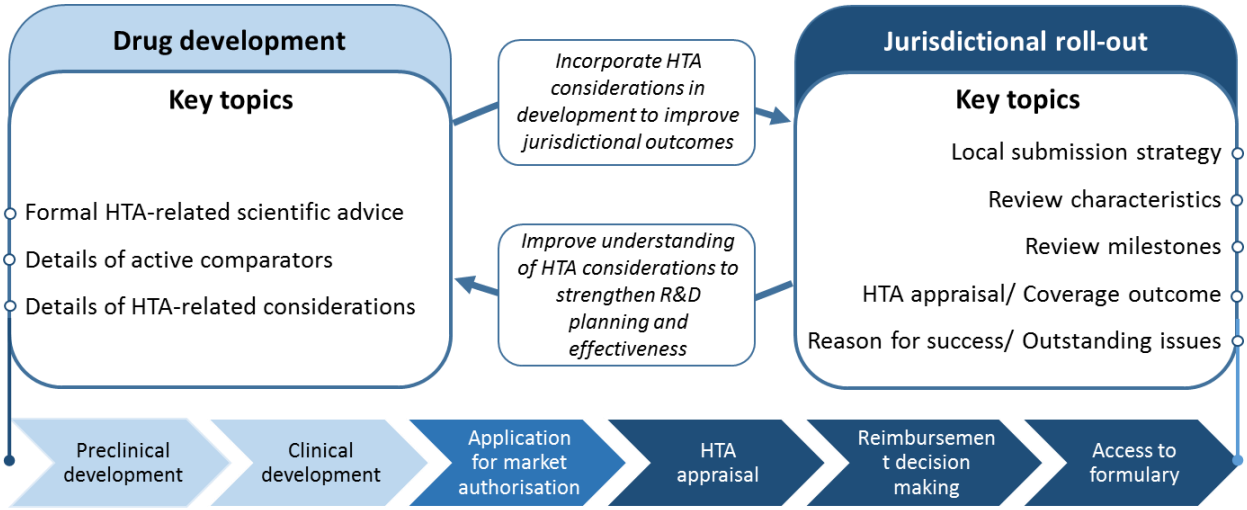
- Strong methodology designed by companies for companies to collect metrics that can provide insights on key issues in the HTA area
- Centralised platform that collects both selective development and jurisdictional metrics with the ability to associate the development strategy with access recommendations
- Annual study cycle to ensure the continuity of the metrics collection and ability to track products through their lifecycle
- Expertise to interpret the data and ability to link other CIRS metrics databases to add value to the study outcomes
- Key learnings of the study provide insights to guide other topic-specific surveys and projects
- High-level outcomes of the study provide credible and independent data with which to inform HTA agency policies and requirements

Key analyses address important business questions

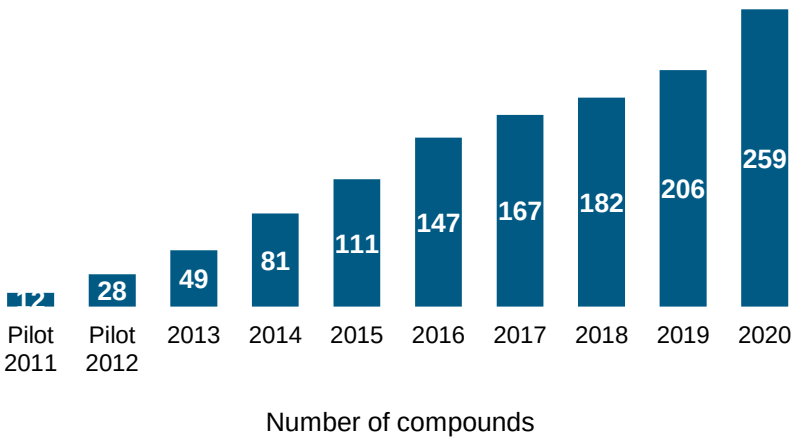
- Types and outcomes of early HTA-related advice and pre-submission consultations
- HTA considerations that have been included in drug development programmes
- Inclusion of active comparators during development and the acceptance by HTA agencies
- Regulatory and reimbursement route and impact on timelines
- HTA review characteristics and outcome comparisons across jurisdictions

CIRS HTA Industry Metrics Programme 2022

Key metrics collected in the programme



Growth of the HTA metrics database



Countries of interests

- Australia
- Canada (national)
- England
- France
- Germany
- Italy (national)
- Spain (national)

- Established core participating companies
- A continually growing database of over 200 compounds
- Observations from a growing cohort of companies and products through anonymised aggregated data collection
- Robust datasets that track compounds from development to jurisdictional roll-out
- Ability to associate development activities with HTA outcomes at the jurisdictional level
- Assessments of the value of taking HTA scientific advice
- Data collection focussed on key international jurisdictions with milestone data pre-filled by CIRS
- Streamlined data collection parameters designed to address key questions and challenges posed by the evolving HTA environment while easing data provision by participants
- Flexible data collection tools (on- and offline) with a new online data collection system
- Annual Focus Study: Designed to answer a topical question of importance to the participants

SUMMARY OF THE DELIVERABLES OF THE 2021 HTA INDUSTRY METRICS PROGRAMME

The HTA Industry metrics programme package is available for a participation fee of £17,500 for 2022.

HTA Industry Metrics Programme: Key deliverables

HTA Industry Metrics Database

The database tracks metrics from development to jurisdictional outcome for new active substances (NASs) and major line extensions (MLEs).

- Provision of specialised training in the use of the database

Annual Executive Summary and Report

Provision of a company-specific report and an Executive Summary of the observations from the benchmarking project, along with the key outcomes from data analyses through 2022

Annual Focus Study

Provision of results from the annual focused study on a topic of interest to participanting companies.

Industry Discussion Meeting *

The annual Industry Discussion Meeting is held each year. At these meetings, participating companies engage in interactive discussions regarding the most recent data analyses, trends in the targeted markets, and activities and results related to the Focus Study.

- Industry Discussion Meeting agenda
  - HTA metrics database: review of trend analyses on factors impacting development and access timelines and outcomes
  - Participant feedback on the analyses and output and reflection on the trends
  - Recommendations for ongoing evolution of the metrics collection programme

* Industry Discussion Meeting: Annual fee includes meeting registration for up to two company representatives. Each participant is responsible for their travel and accommodations.

Communication

- Periodic updates on ongoing activities relating to the use of the data collection tools
- Discussion and feedback on the changes of the data collection parameters
- Update on any outcomes of HTA body visits and to arrange Insight Seminars at participating companies