Lumanity | PHARMO
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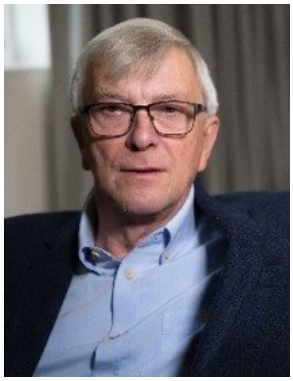
Minimize the risk of payers rejecting your clinical trial surrogate endpoints by leveraging real world evidence

Lumanity and The PHARMO Institute delivers research insights into validation of surrogate endpoints in clinical trials within a real world setting.



Prof. Ron Akehurst, Executive Chair, HEOR

"Surrogate endpoints often pose a huge challenge for payers. HTA agencies consistently see endpoints selected in trials which are convenient for the sponsor but lack convincing evidence on their relationship to outcomes of interest for payers, healthcare professionals, and patients. This creates uncertainty for payers and often leads to rejections, restricted approvals, and commercial delays. The right kind of Real World Evidence is a valuable and underused tool which can help manage this uncertainty."

Ron is an academic health economist and former Dean of ScHARR, University of Sheffield, is a member of the Rare Diseases Advisory Group of NHS England and was a member of the National Institute for Health and Care Excellence (NICE) technology appraisal, and other, committees for 23 years.

Lumanity approach

Companies working with a novel endpoint with minimal payer and HTA precedence should reach out to the Lumanity experts to discuss de-risking strategies.

Assessment of payer acceptance surrogate endpoint

When assessing potential surrogate endpoints, companies in category A or B should highly consider reaching out to Lumanity for advice:

A. Novel endpoint; no payer/HTA presence of endpoint acceptance

B. Inconsistent feedback from payers/HTAs

C. Payer/HTA precedence of endpoint acceptance

With the PHARMO Institute partnership, Lumanity can leverage clinically rich long-term RWD which enables validation of surrogate endpoints and provide confidence to payers.

Real world evidence is one part of our overall de-risking strategy which includes:

- Meta-analysis of randomized clinical trials based on a systematic reviews of clinical literature
- Analysis of patient level data from trial of interest and previous clinical trials (if available)
- Additional country specific and pan-European RWE studies
- Clinical and payer expert opinion

Surrogacy estimation requires long-term follow-up data, granular clinical information on outcomes, and detailed population characteristics which is often not captured in real-world data.

Why PHARMO Institute

A unique, longitudinal, and clinically rich dataset

- 2002 onwards (20+ years)
- Ability to follow through multiple healthcare settings
- Data regularly updated and expanded to include new patients and follow-up information

Data linkages enable identification of surrogate and long-term relevant endpoints

- Pathology registry (e.g. biopsy, gene sequence, cytology/histology results)
- Clinical labs (e.g. blood tests, lipoproteins, cholesterol)
- Cancer registry (e.g. tumour characteristics, progression-free survival)
- Mortality registry (e.g. overall survival)
- Unstructured free text notes (from general practitioner data)

Pan-European capability

- Our global data partner network can access diverse sources of pan-European real-world data on >100 million patients

Examples of challenging surrogate endpoints which RWE can support

Therapeutic area	Surrogate Endpoints	Stakeholder relevant endpoints
Oncology	Objective response, progression-free survival, DoR, metastases free survival	Overall survival, quality of life
Cardiovascular	Lipoprotein/cholesterol, increase in blood flow, ejection fraction, ATTR level	Cardiovascular events (MACE, stroke, heart failure, death)
Nephrology	Kidney volume, change in eGFR, and creatinine levels	Time to end-stage renal disease, change in quality of life
Duchenne Muscular Dystrophy	MRI results, change in dystrophin levels	Patient-function; hospitalizations for surgery

Concerned about your surrogate endpoint selection?

Reach out to Lumanity for a complimentary consultation. Our in-house experts can be counted on for service and quality. We utilize our tried and tested approaches to produce high-quality services, with guaranteed satisfaction.

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