

Health Technology Assessment

Evidence Generation

Access & Strategy

Reimbursement

Value Communication



Discovering the
patient journey using
Real World Evidence

COVANCE MARKET ACCESS
Experience *Forward Thinking*

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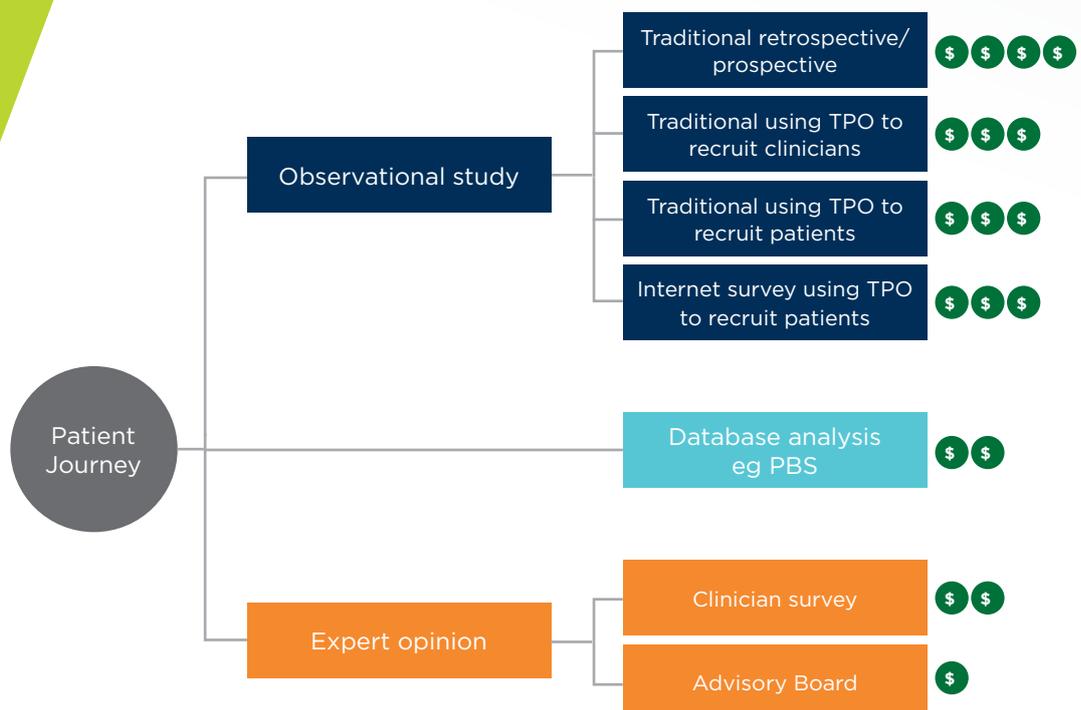
UNDERSTANDING THE PATIENT PATHWAY

The need for Real World Evidence (RWE) to support Market Access objectives is increasing as Pharma and Biotech seek to understand treatment patterns prior to introducing a new product, and afterwards to confirm the comparative effectiveness.

The range of methods available vary in terms of timeframe, cost and rigour.

Covance offers a range of study designs for gathering these data. We have recently had successful experiences with two new methodologies for primary data collection which can be completed within a shorter timeframe and lower cost relative to a standard chart audit. These methodologies involve partnering with third party organisations (TPOs) to recruit:

- ▶ **Clinicians** who will complete patient surveys or case report forms
- ▶ **Pharmacies** who can recruit patients, at the point of dispensing to:
 - Complete a short questionnaire about their condition or treatment at the pharmacy; or
 - Agree to be contacted to assess eligibility to participate in a larger observational study.



WHICH METHOD SHOULD I USE?

Traditional chart review (or audit)

- ▶ Able to collect specific in-depth data
- ▶ Can be longitudinal
- ▶ Can be long timeframe

Chart review using TPO to recruit clinicians

- ▶ Able to collect specific data
- ▶ Can be longitudinal
- ▶ Can recruit a large number of clinicians (3-5 patients per clinician)
- ▶ Fast timeframe

Pharmacy-based patient survey

- ▶ Pharmacies recruit patients at time of dispensing
- ▶ Good for short surveys
- ▶ Very short timeframe

Existing data (database analysis)

- ▶ Large number of patients
- ▶ Can investigate a large number of therapeutic areas
- ▶ Fast timeframe

Internet-based patient survey

- ▶ TPO recruits patients from online panel
- ▶ Can be longitudinal
- ▶ Requires ethics approval

Expert opinion

- ▶ Good for understanding treatment algorithm
- ▶ Best for specialist disease, likely to be representative of wider practice
- ▶ Fast timeframe

	Traditional chart review (or audit)	Chart review using TPO to recruit clinicians	Pharmacy-based patient survey	Existing data (database analysis)	Internet-based patient survey	Expert opinion
Contracting	With each site	With TPO	With TPO	✗	With TPO	✗
Ethics	✓	[a]	[a]	EREC	✓	✗
Protocol/SAP	✓	✓	✓	✓	✓	✗
Typical sample size	1-5 sites 30-500 patients	50-100 clinicians 150-500 patients	50-100 pharmacies 500-1000 patients	10% of Australian population	100-300 patients	10-50 clinicians
Data collection	site	clinician	pharmacist/patient	PBS dispensing data	patient	clinician
Amount of information collected	Unlimited [b]	Up to 30 minutes per patient (-5 pages)	Up to 5 minutes per patient (5-10 questions)	Limited to availability within database	Unlimited [b]	15-30 minutes per clinician
PROs	✗	✗	✓	✗	✓	✗
Data cleaning/query	[c]	✗	✗	✗	✗	✗
Typical Timeframe	18 months	6 months	2 months	1 months	6-12 months	1-2 months
Cost	\$\$\$\$	\$\$\$	\$\$\$	\$	\$\$\$	\$-\$\$

EREC, External Request Evaluation Committee; PRO, patient reported outcomes; SAP, statistical analysis plan; TPO, third party organisation

[a] Typically ethics not required as the study is run in conjunction with Market Research vendor

[b] Sites/patients are compensated for time taken and therefore the data collection tool may be quite lengthy depending on study objectives

[c] Inconsistent answers may be queried with site staff

CASE STUDIES

1 Traditional retrospective study: MRU and costs among Australian patients with hepatitis C

- ▶ **Objective:** To evaluate medical resource utilization (MRU) and associated costs among Australian patients with genotype 1 chronic hepatitis C.
- ▶ **Design:** Retrospective observational study. Review of medical records of 702 patients attending three medical clinics.
- ▶ **Steps:** After governance (contracting) and ethics approval, site staff reviewed hospital database and case notes for information on treatment patterns, including reason(s) for delaying treatment for all patients and comprehensive MRU for a stratified random sample of patients. Data entry was performed at the site with study design, data management, analysis and reporting performed by Covance.
- ▶ **Primary results:** When findings were compared with previous published Australian estimates based on expert opinion, the estimates indicate that the cost of care may be higher than previously thought.
- ▶ **Business Impact:** Informed the cost-effectiveness, financial implications and price negotiations for the new treatment.
- ▶ **Reference:** McElroy HJ, et al. J Med Econ 2017; 20(1):72-81.

2 Traditional study using TPO to recruit clinicians: Pain relief timelines in six EU countries and Australia

- ▶ **Objective:** To characterise current pain relief treatment timelines in patients in medical emergencies.
- ▶ **Design:** Retrospective observational study in 6 EU countries plus Australia. Review of 856 patients by 189 emergency care physicians. Clinicians recruited in each country by a TPO.
- ▶ **Steps:** Once recruited by the TPO, emergency care physicians were asked to identify their last 3-5 eligible patients and review those patients' charts to report anonymized patient-level information on treatments and outcomes via an online survey hosted by the TPO. Study design, analysis and reporting was performed by Covance.
- ▶ **Primary results:** Time to pain relief treatment significantly shorter in Australia compared with 6 EU countries.
- ▶ **Business Impact:** Informed the clinical need for fast pain relief.
- ▶ **Reference:** Xia A, et al. Poster accepted for XIth European Congress of EUSEM, 2017, Athens, Greece.

3

Traditional study using TPO to recruit patients: Assessing the relationship between medication regimen and adherence

- ▶ **Objective:** To understand the impact of the mode of drug administration on adherence and quality of life.
- ▶ **Design:** A questionnaire was administered to 1000 patients recruited from pharmacies at point of dispensing
- ▶ **Steps:** Once implemented within the dispensing software by the TPO, pharmacists recruited eligible patients to answer 5-10 questions [Study design, analysis and reporting by Covance.]
- ▶ **Primary results:** Patients who were on twice daily dosing missed on average 36% more doses compared with patients on a once daily dosing regimen.
- ▶ **Business Impact:** Sponsor was able to introduce practices to increase adherence.

PUBLICATIONS

Below is a selection of our RWE work conducted in Australia.

Xia A, Dickerson S, Dunlop W, Szende, A, Colman S. Impact of using low-dose methoxyflurane on time from arrival of paramedic / emergency assistance to first pain relief treatment versus other pain medications in Australia. Poster accepted for XIth European Congress of Emergency Medicine (EUSEM), September 23-27, 2017, Athens, Greece.

Xia A, Nokela M, Liebmeier M, Szende A, Colman S. Pre-hospital pain relief treatment in patients with musculoskeletal injuries experiencing moderate to severe pain in medical emergencies. Poster presented at: 20th Annual European Congress of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR); November 4-8, 2017; Glasgow, Scotland.

McElroy HJ, Roberts SK, Thompson AJ, Angus PW, McKenna SJ, Warren E, Musgrave S.. Medical resource utilization and costs among Australian patients with genotype 1 chronic hepatitis C: results of a retrospective observational study. *J Med Econ.* 2017;20(1):72-81.

Ahmad H, Taylor BV, van der Mei I, Colman S, O'Leary BA, Breslin M, Palmer AJ. The impact of multiple sclerosis severity on health state utility values: Evidence from Australia. *Mult Scler.* 2017;23(8):1157-1166.

Colman S, O'Leary BA, Palmer AJ, Simmons R. The Impact of Multiple Sclerosis Severity on Quality of Life, Stress, Depression and Social Support Needs. Poster presented at 6th Asia-Pacific Conference of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR), September 6-9 2014; Beijing, China.

Davis A, Bird R, Brighton T, McRae S, McElroy H, Quinn S, Lawrinson S. A descriptive analysis of treatment in adult patients with chronic, primary immune thrombocytopenia (ITP) diagnosed since 2005. Poster presented at: Haematology Society of Australia and New Zealand (HSANZ) 2013 Joint Scientific Meeting, October 2013; Gold Coast, Australia.

O'Leary BA, Colman S, Ruth A, Kotapati S, Cook G. Treatment patterns among patients with advanced melanoma: a retrospective longitudinal study. Poster presented at 4th Asia-Pacific Conference of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR), September 2010., Phuket, Thailand.

Colman S, Strizek A, O'Leary BA, Ruth AJ, Cook GA. Treatment patterns among patients with advanced breast cancer previously treated with an anthracycline and a taxane: a retrospective longitudinal study. Poster presented at 12th Annual European Congress of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR), October 2009, Paris, France.

O'Leary BA, Daja MM, Adena MA. Chart audit of the dose and effectiveness of long acting insulin analogues in Australian clinical practice. Poster presented at 12th Annual European Congress of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR), November 2009, Athens, Greece.

O'Leary BA, Colman S, Ruth A-J, Cook GA. Heterogeneity in the approach taken to conducting chart audits in Australian hospitals. Poster presented at 12th Annual European Congress of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR), November 2009, Athens, Greece

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