# From Approval to Publication: Study Types and Timeframes using the UK Clinical Practice **Research Datalink**

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# Objective

To investigate the types of studies conducted using the UK Clinical Practice Research Datalink (CPRD) and the time from their approval to publication.

#### **FIGURE 1**

Matched studies by year of protocol approval and type of research



# Background

- Timely access to reliable real-world data (RWD) is critical for producing high quality evidence to inform decision making. However, the accessibility and usability of databases varies.
- CPRD is a UK Government research service, which collates data from >2,000 UK primary care practices. The data available includes demographics, diagnoses, symptoms, drug exposures and referrals; the database is extensively utilised, having contributed to >3,500 peer-reviewed publications since 1988.<sup>1</sup>
- While the CPRD is a valuable data source, timelines for data access are not clearly documented. Time from protocol submission to first outcome is reported; however, important metrics such as time from submission to approval and approval to data release, are not available.<sup>2</sup>
- This study aimed to analyse the types of studies conducted using the CPRD and the duration required for these to be published post-approval, which is likely correlated with time from approval to data release.

## Methods

- CPRD protocols approved between January 2019–December 2021 were matched with studies published between January 2019– April 2024 in the CPRD bibliography. December 2021 was selected as a cut-off to allow time for subsequent publication.
- Protocols and publications were manually matched using technical summaries and approval IDs. For each publication,

#### FIGURE 2

#### Matched studies by year of publication



research type and disease area were extracted, and time from approval to publication was calculated.

### Results

- 294 approved protocols were matched with publications; 423 could not be matched (47.5%, 63.3% and 76.2% were clinical, epidemiological and economic research studies, respectively).
- For matched studies, clinical and epidemiological research were most frequent (53.7% and 35.7%, respectively), while economic research was less common (10.5%) (**Figure 1**).
- Publications in endocrine and cardiovascular research were most common (18.0% and 16.6%, respectively) (**Figure 2**). Other areas included oncology (9.8%), neurology (9.2%), respiratory (8.1%), mental health (6.4%), musculoskeletal/orthopaedics (5.8%) and COVID-19 (4.8%).
- Across the three years, mean (standard deviation) time from approval to publication was 2.2 (1.0) years, with little variation between study types, ranging from 2.1 (1.0) to 2.4 (0.8) for epidemiological and economic studies, respectively (Table 1).
- During COVID-19 (March 2020–December 2021), a spike in publications on mental health and COVID-19 were observed. Publications in disease areas like neurology and oncology steadily increased with time from protocol approval (Figure 2).

## Conclusion

\*Infectious diseases or respiratory diseases excluding COVID-19. The number of publications on COVID-19 have been presented separately.

#### TABLE 1

#### Time to publication by year of protocol approval and study type

Year of approval, study type		Number of publications	Time to publication (years)					Proportion of protocols
			Mean	Median	SD	IQR	Range	not matched to publications (%)
2019	All	152	2.39	2.38	1.10	1.58	0.14-4.73	46%
	Clinical	85	2.33	2.09	1.15	1.79	0.14-4.57	36%
	Economic	15	2.73	3.01	0.80	0.95	1.15-4.02	63%
	Epidemiological	52	2.43	2.45	1.04	1.42	0.21-4.73	52%
2020	All	60	1.95	2.04	1.02	1.38	0.09-3.80	60%
	Clinical	27	2.24	2.29	0.99	1.65	0.61-3.80	54%
	Economic	6	2.04	2.03	0.76	0.66	1.13-3.31	78%
	Epidemiological	27	1.80	1.86	0.92	1.38	0.09-3.66	58%
2021	All	82	1.83	1.93	0.70	1.05	0.26-3.17	71%
	Clinical	46	1.79	1.95	0.77	1.09	0.26-3.17	58%
	Economic	10	2.04	2.29	0.61	0.94	0.97-2.58	84%
	Epidemiological	26	1.77	1.80	0.60	0.62	0.40-2.90	77%
Total		294	2.16	2.11	0.99	1.31	0.09-4.73	59%

CPRD data support clinical and epidemiological research in disease areas that reflect the UK's evolving health priorities.

Completing studies that utilise CPRD data can be a lengthy process. Average times presented from this analysis are likely underestimated, as 58.9% of protocols could not be matched to publications indicating that some studies might still be ongoing at the time of analysis. While reasons for extended timelines to publication are not reported by CPRD, delays during study execution and data access post-CPRD approval could be contributing.

Providing more clarity on average wait times for CPRD review, approval and data release may be beneficial to inform study planning.

Orange shading represents the longest mean time to publication and highest proportion of unmatched protocols, while blue represents the shortest mean time to publication and lowest proportion of unmatched protocols.

Abbreviations: CPRD: Clinical Practice Research Datalink; IQR: interquartile range; RWD: real-world data; SD: standard deviation; UK: United Kingdom.

References: 1CPRD (2022). Bibliography. Available at: https://www.cprd.com/bibliography [Last accessed 21 Aug 24]; 2CPRD (2021). Independent Scientific Advisory Committee (ISAC) Annual Report. Available at: https://www.cprd.com/sites/default/files/2022-03/MHRA\_ISAC%20Annual%20Report%202020-2021\_0.pdf [Last accessed 21 Aug 24]. **Acknowledgements:** The authors thank Fay Angel, Costello Medical, for graphic design assistance.

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