Estimating clinical research project duration from idea to publication

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Accepted 27 April 2021
Published Online First 14 May 2021

To cite: Tumin D, Brewer KL, Cummings DM, *et al*. *J Investig Med* 2022;**70**:108–109.

The scientific response to the COVID-19 pandemic has elicited commentaries on the quickening of biomedical research,[1–3] contrasting with literature on prolonged time to publication for clinical research projects.[4–6] We investigated research project duration for three clinical departments (emergency medicine, family medicine, and pediatrics) with centralized research leadership in a community-based US medical school. Following institutional review board (IRB) approval, we identified original research reports published or accepted in academic year 2019–2020, originating at our institution, and involving faculty from these departments. Of 39 eligible publications, we reconstructed study timelines (table 1) for 17 publications based on departmental records, and 10 publications based on a survey of corresponding authors.

The median overall project duration was 18 months (IQR 10–26). Median durations of specific phases were 2 months for project development (IQR 1–4), 6 months for execution (IQR 1–18), 2 months for writing (IQR 1–4), and 4 months for publication (IQR 2–5). Durations are compared by project type and stage in table 2. On multivariable Cox regression analysis, time to publication was prolonged for prospective versus retrospective projects (HR of publication 0.14, 95% CI 0.02 to 0.83, p=0.030) and funded versus unfunded projects (HR 0.13, 95% CI 0.02 to 0.80, p=0.027). Twelve articles were accepted or published during the COVID-19 pandemic (April–June 2020). Median project duration was longer compared with pre-COVID publications in our sample (20, IQR 19–25 months, vs 13, IQR 9–40 months), but this difference did not reach statistical significance (rank-sum p=0.271).

Qualitatively, centralized research support programs have been described as 'expediting' clinical research[7] by addressing limitations of time, funding, and expertise among investigators.[8–10] Short-term evaluations of such programs (<2 years) have focused on activities which can be completed in a few months, such as IRB protocol or grant submission[8]; or manuscript submission, but not necessarily publication.[10] Indeed, within this time frame, many projects receiving central support may not reach publication. We propose that tracking project duration from conception to publication, in addition to discrete steps such

Table 1 Data points on project stages, by project type

Project stage	Number of projects with available data			
	Prospective research	Retrospective research	Basic science research	Other project type
Conception First written outline or synopsis of project rationale and aims	5	18	1	2
Funding First funding received in direct support of the project	2	5	1	0
Regulatory submission First submission to IRB/IACUC	5	8	1	0
Regulatory approval Receipt of all approvals needed to conduct the project	4	9	1	0
Start of data collection	5	18	1	1
End of data collection	4	18	1	1
Manuscript draft First draft of manuscript, including introduction, methods, and results	5	18	2	2
Manuscript submission First submission of manuscript to peer-reviewed journal	5	18	2	2
Manuscript acceptance* Date of acceptance decision from journal	5	18	2	2
Publication date Date of earliest publication online or in print	4	17	2	2

*Data set included two prospective studies, nine retrospective studies and one basic science study accepted on or after April 1, 2020.
IACUC, Institutional Animal Care and Use Committee; IRB, institutional review board.

Table 2 Project duration (in months) by project characteristics (N=27)

	Median (IQR) project duration (months)				
Characteristic	**Total**	**Development**	**Execution**	**Writing**	**Submission**
Project type					
Retrospective	17 (11–19)*	2 (<1–4)	2 (1–9)	2 (1–4)	3 (2–5)
Prospective	42 (24–42)*	5 (2–8)	20 (7–28)	9 (2–15)	4 (4–7)
Bench science or other	7 (5–24)*	6 (<1–12)	12 (1–23)	1 (1–2)	3 (<1–4)
Regulatory approval required					
No	11 (5–19)†	<1 (<1–4)	1 (<1–3)†	2 (1–3)	3 (2–5)
Yes	20 (17–38)†	3 (2–5)	7 (2–26)†	2 (1–6)	4 (3–5)
External funding received					
No	16 (9–20)‡	2 (<1–4)‡	2 (1–9)‡	2 (1–4)	3 (2–4)‡
Yes	38 (29–58)‡	9 (5–12)‡	25 (15–27)‡	1 (1–12)	7 (6–14)‡
Trainee participation					
No	16 (5, 24)	<1 (<1–4)	2 (1, 7)	3 (1, 8)	2 (1, 4)
Yes	19 (11, 32)	2 (1, 4)	7 (2, 22)	2 (1, 4)	4 (3, 5)
Prior presentation					
No	18 (10, 19)	3 (1, 4)	2 (1, 8)§	2 (1, 4)	3 (2, 5)
Yes	21 (11, 40)	2 (<1, 5)	7 (3, 26)§	2 (1, 4)	4 (3, 6)

*Statistically significant difference across project types (p<0.05) on Kruskal-Wallis test.
†Statistically significant difference according to need for regulatory approval (p<0.05) on rank-sum test.
‡Statistically significant difference according to receipt of external funding (p<0.05) on rank-sum test.
§Statistically significant difference according to prior presentation (p<0.05) on rank-sum test.

as conference presentation or grant submission, can help identify opportunities for improving the research process for investigators.

Our data also have important implications for faculty career development and mentorship. In light of the typical research project duration, pursuing projects concurrently rather than sequentially is important for building a strong file for promotion and tenure. While faculty with extramural funding ultimately tend to achieve higher academic productivity,[11 12] an important finding was that grant-funded research took significantly longer from conception to publication than unfunded research. Delays on grant-funded projects may be addressed by optimizing institutional grant-related processes and developing a diverse portfolio of funded and unfunded research. Lastly, we present an early comparison of project duration for publications accepted before and during the early months of the COVID-19 pandemic. Considering the long life cycle of a typical project, the impact of the pandemic on project duration and publication is likely to continue accumulating in the months ahead and may pose serious career challenges for active scientists.

Correction notice This article has been corrected since it was first published to include the Institutional Review Board approval ID.

Contributors All authors participated in study conceptualization and design. DT, KB and DC participated in data collection. DT performed data analysis and drafted the manuscript. KB, DC, KK and KC interpreted the results and critically revised the manuscript. All authors approved the final version to be submitted.

Funding The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.

Competing interests None declared.

Patient consent for publication Not required.

Ethics approval The Institutional Review Board approval ID is UMCIRB 20-002220.

Provenance and peer review Not commissioned; internally peer reviewed.

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