Is there a need for review-a-thons?

the authors' figure appears to show a pacemaker implantation rate at 10 years that is very similar to the French (70%) and US registries (75%).[3,6] Finally, the analysis of the US registry[4] and the recent meta-analysis[5] showed that fluorinated steroids do not prevent pacemaker implantation.

Although we remain unconvinced that close follow-up is beneficial in terms of treatments and outcomes, we fully agree with the authors about the importance of expert centres establishing research protocols and reporting data to enable their experience to contribute to the findings about this rare condition. In particular, we eagerly await data concerning the development of home monitoring.

We declare no competing interests.

*Nathalie Costedoat-Chalumeau, Nathalie Morel
nathalie.costedoat@aphp.fr

Assistance Publique-Hôpitaux de Paris, Cochin Hospital, Internal Medicine Department, Referral Center for Rare Autoimmune and Systemic Diseases, Paris 75014, France (NC-C, NM); and Centre of Research in Epidemiology and Statistics, Institut National de la Santé et de la Recherche Médicale, Institut National de la Recherche Agronomique, Université de Paris, Paris, France (NC-C)

1 Costedoat-Chalumeau N, Morel N, Fischer-Betz R, et al. Routine repeated echocardiographic monitoring of fetuses exposed to maternal anti-SSA antibodies: time to question the dogma. *Lancet Rheumatol* 2019; **1:** e187–93.
2 Morel N, Levesque K, Maltret A, et al. Incidence, risk factors, and mortality of neonatal and late-onset dilated cardiomyopathy associated with cardiac neonatal lupus. *Int J Cardiol* 2017; **248:** 263–69.
3 Izmirly PM, Saxena A, Kim MY, et al. Maternal and fetal factors associated with mortality and morbidity in a multi-racial/ethnic registry of anti-SSA/Ro-associated cardiac neonatal lupus. *Circulation* 2011; **124:** 1927–35.
4 Izmirly PM, Saxena A, Sahl SK, et al. Assessment of fluorinated steroids to avert progression and mortality in anti-SSA/Ro-associated cardiac injury limited to the fetal conduction system. *Ann Rheum Dis* 2016; **75:** 1161–65.
5 Hoxha A, Mattia E, Zanetti A, et al. Fluorinated steroids are not superior to any treatment to ameliorate the outcome of autoimmune mediated congenital heart block: a systemic review of the literature and meta-analysis. *Clin Exp Rheumatol* (in press).
6 Levesque K, Morel N, Maltret A, et al. Description of 214 cases of autoimmune congenital heart block: results of the French neonatal lupus syndrome. *Autoimmun Rev* 2015; **14:** 1154–60.
7 Fredi M, Andreoli L, Bacco B, et al. First report of the Italian registry on immune-mediated congenital heart block (Lu.Ne registry). *Front Cardiovasc Med* 2019; **6:** 11.

Is there a need for review-a-thons?

"IMI's EHDEN project dramatically demonstrated the power of using clinical data in research by replicating, during a five-day 'study-a-thon', the results of a systematic review covering 20 years of research, and a multi-year clinical trial."[1] In this quote the Innovative Medicine's Initiative (IMI) newsroom refers to the results of a recently published population-based network study, which reported on opioid use, postoperative complications, and implant survival after unicompartmental versus total knee replacement.[2] Is it possible that within 5 days, approximately 300 pages of study documentation (a study protocol comprised of 259 pages,[3] a published paper,[2] 30 pages of appendices,[2] and numerous of pages of R-syntaxes) were created?[3]

The project looks very transparent, but an adequate peer-review seems like a very time-consuming process. Personally, I spent at least 30 min comparing the methods section of the paper[2] with the study protocol.[3] Section 8.2 of the study protocol lists six different data sources;[3] however, the published paper only mentions five data sources. Why were the Medicaid patients not included in the published article?[2] There is also a seventh bullet-point listed to "add others" in section 8·2 of the study protocol.

Given the short time-window of follow-up to record events, how reliably was the actual date of surgery recorded in the published paper? I have some experience with a large UK primary care database in this area and as far as I can see, the authors do not provide any information on the date of surgery. Was the reliability of the recording of start of follow-up different for the data sources from the USA? How was the start of follow-up defined; as the actual date of surgery, the date of hospital admission, the date of discharge, or the date when the record was filed? Has this definition ever been validated? How was the end of the follow-up defined in each individual data source? Do any of the USA data sources overlap? If not, how do we know? Furthermore, how was the outcome "opioid use" being operationalised? Section 8.5.6 of the study protocol lists the following products "heroin, hydrocodone, and opioids"; however, does this list also include codeine, which is often used to reduce coughing rather than for pain relief? Some or maybe all these answers might be hidden somewhere in the 300 pages of documentation or in the R-syntaxes. Operational definitions and computer syntax are probably not materials that the readers of *The Lancet Rheumatology* would consider looking at, but they can substantially affect the associations and conclusion. Is there a need for review-a-thons to critically appraise study-a-thons?

I declare no competing interests.

Frank de Vries
frank.de.vries@mumc.nl

Department of Clinical Pharmacy and Toxicology, Maastricht University Medical Centre, Maastricht 6229, Netherlands

1 Innovative Medicines Initiative. Can real world data replicate a clinical trial? EHDEN study suggests yes. https://www.imi.europa.eu/news-events/newsroom/can-real-world-data-replicate-clinical-trial-ehden-study-suggests-yes (accessed Nov 29, 2019).
2 Burn E, Weaver J, Morales D, et al. Opioid use, postoperative complications, and implant survival after unicompartmental versus total knee replacement: a population-based network study. *Lancet Rheumatol* 2019; **1:** e229–36.
3 Burn E, Weaver J. Morales D, et al. Prospective validation of a randomised trial of unicompartmental and total knee replacement: real word evidence from the OHDSI network. 2018. https://github.com/OHDSI/StudyProtocols/blob/master/UkaTkaSafetyEffectiveness/documents/OHDSI%20Oxford%20PLE%20Protocol%2030dec2018.docx (accessed March 1, 2020)

Authors' reply

We would like to take this opportunity to respond to the Correspondence by Frank de Vries. We would like to