

ICMJE又放大招——Data sharing statements for clinical trials

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BMJ 2017 ; 357 doi: <https://doi.org/10.1136/bmj.j2372> (Published 05 June 2017)

Cite this as: BMJ 2017;357;j2372

临床流行病学和循证医学

什么?临床试验要求研究者share数据了?谁这么大胆呢?想当年PLOS ONE杂志要求作者提供数据在学术界可谓是掀起了轩然大波。这会儿又是谁能在大名鼎鼎的BMJ上发表社论要求大家公开(共享)临床试验数据?

你问这到底是哪位有实力的大哥，有胆魄提这样的要求?当然是the International Committee of Medical Journal Editors，国际医学期刊编辑委员会。我们来看看这位大哥有哪些成员，随便列出四个就能让大家仰视他的地位:NEJM、Lancet、JAMA、BMJ都是ICMJE的成员之一。而且上面截图这篇社论不仅在BMJ上刊出了，还在NEJM、Lancet、JAMA等成员期刊上同时刊出。是不是足见这位大哥的江湖地位?想当年，就是这位大哥和WHO一起提出临床试验必须提前在公开的网络注册平台上进行试验注册。也就是他们发出的英雄帖让我们转变我们的研究流程，重视临床研究注册，并关注WHO的临床试验注册平台。那么，到底这会儿大哥对我们提出了什么新要求呢?

第一，对于2018年7月及以后提交到ICMJE期刊的临床试验报告，必须包含数据共享声明。

第二，对于2019年1月1日后开始入组受试者的临床试验，必须在临床试验注册平台上提交数据共享计划。如果数据共享计划有变化或更改应在注册平台上进行更新并在提交论文时加以说明。

那么数据共享声明包含声明内容呢?以下内容必须包含在数据共享声明中：1. 是否共享研究对象的个体数据(包括变量清单);2. 会共享哪些数据;3. 研究相关的文档(研究方案、统计分析计划)是否

共享;4.数据将什么时间可获取以及可开放获取多长时间;5.对共享试验数据的入选要求(包括谁能获取数据、试验数据可用于什么分析);

研究者一定要注意，期刊编辑会参考研究者提供的数据共享声明来做出编辑对稿件是否刊出的决定。而且上面那5点要求是对数据共享声明的最低要求，ICMJE的某些期刊会要求更为严格试验数据共享。

ICMJE还举了四个例子其中有最为开放的数据共享声明和最为保守的数据共享声明供大家参考。

Table. Examples of Data Sharing Statements That Fulfill These ICMJE Requirements*

	Example 1	Example 2	Example 3	Example 4
Will individual participant data be available (including data dictionaries)?	Yes	Yes	Yes	No
What data in particular will be shared?	All of the individual participant data collected during the trial, after deidentification.	Individual participant data that underlie the results reported in this article, after deidentification (text, tables, figures, and appendices).	Individual participant data that underlie the results reported in this article, after deidentification (text, tables, figures, and appendices).	Not available
What other documents will be available?	Study Protocol, Statistical Analysis Plan, Informed Consent Form, Clinical Study Report, Analytic Code	Study Protocol, Statistical Analysis Plan, Analytic Code	Study Protocol	Not available
When will data be available (start and end dates)?	Immediately following publication. No end date.	Beginning 3 months and ending 5 years following article publication.	Beginning 9 months and ending 36 months following article publication.	Not applicable
With whom?	Anyone who wishes to access the data.	Researchers who provide a methodologically sound proposal.	Investigators whose proposed use of the data has been approved by an independent review committee ("learned intermediary") identified for this purpose.	Not applicable
For what types of analyses?	Any purpose.	To achieve aims in the approved proposal.	For individual participant data meta-analysis.	Not applicable
By what mechanism will data be made available?	Data are available indefinitely at (Link to be included).	Proposals should be directed to xxx@yyy. To gain access, data requestors will need to sign a data access agreement. Data are available for 5 years at a third party website (Link to be included).	Proposals may be submitted up to 36 months following article publication. After 36 months the data will be available in our University's data warehouse but without investigator support other than deposited metadata. Information regarding submitting proposals and accessing data may be found at (Link to be included).	Not applicable

* These examples are meant to illustrate a range of, but not all, data sharing options.

文章的最后作者还进行了展望，希望共享去标识的研究数据会成为一种常态，使我们能从临床试验中参与者的努力和牺牲中获取更多的知识。

看到ICMJE的这个新声明、新要求不得不让人佩服编辑们的魄力，可想而知，推动数据共享会多么艰难，这个推动过程可能会遇到很多阻力。但是我们希望这个工作能像临床试验注册一样逐渐被研究者重视、接受、践行。可以说这体现了医学科学研究出口管理的意志，让我们的研究更透明，让我们的研究数据能起更大的作用。可以想象，在实现了临床试验数据共享的将来，我们可以通过整合、挖掘、分析这些数据来解决更多的临床问题，来得到更有把握或更可推广的研究结论。真是光想想就让人开心呢。你呢?看到这个社论又有什么想法涌上心头?别忘记通过留言和我们共享哦。

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Published: 05 June 2017

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June 5, 2017

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JAMA. Published online June 5, 2017. doi:10.1001/jama.2017.6514

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参考文献：

Darren B Taichman, Peush Sahni, Anja Pinborg, et al. Data Sharing Statements for Clinical Trials : A Requirement of the International Committee of Medical Journal Editors. NEJM, Lancet, BMJ, et al. 2017.6.

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