We believe that Kepes and McDaniel (2013) are highly accurate in their assessment of the current state of publishing practices in industrial and organizational (I–O) psychology research, and they make several useful recommendations for improvement. The focus of this article is on one of Kepes and McDaniel’s key recommendations—research registries.

Kepes and McDaniel cite examples from medical clinical trial research supporting the idea of maintaining a database of all planned and implemented research, thereby (a) providing a more complete picture of the research in the field (not overly biased in favor of supported hypotheses), and (b) fostering research integrity by encouraging researchers to follow the documented protocol. However, medical research registries have travelled a long, difficult, and incomplete path.

Table 1 shows a few of the major milestones in the widespread adoption of medical registries over the past 45 years. Dickersin and Rennie (2003) note that computerized registries have existed since at least the 1960s, but it took 30 years of interest and discussion in the medical community before serious progress was made toward widespread use. It took Simes’ (1986) seminal article on publication bias in medical research to attract widespread attention to the problem and heighten the importance and need of an international registry for all clinical trials. It is also essential to note that medical registries first took hold with the development of targeted specialty registries, but it took congressional action in the form of the Health Omnibus Programs Extension Act (HOPE) of 1988 mandating the Department of Health and Human Services to develop a data bank.
of research information on “immune defi-
ciency syndrome.” The HOPE Act later
served as the model for the requirements
found in the Food and Drug Admin-
istration Modernization Act (FDAMA) of
1997, which lead to the largest registry in
use, ClinicalTrials.gov (Dickersin & Rennie,
2003). Unfortunately the FDAMA narrowly
defined clinical trials that required registra-
tion and was largely ignored (Dickersin &
Rennie, 2012). It then took another 10 years
until an update to the law, the FDA Amend-
ment Act (FDAAA) of 2007, broadened its
scope and mandated its use.

Registrations have greatly increased dur-
ing the past few years partly as a result of the
International Committee of Medical Journal
Editors’ (ICMJE) policy requiring prospective
registration of medical intervention trials as
a condition of publication (De Angelis et al.,
2004), civil penalties of up to $10,000 a
day for noncompliance, and grant funding
implications for researchers that the FDAAA
(2007) established. Furthermore, in 2006,
the World Health Organization declared
support for clinical trials registration and
launched a registry portal through which
more than a dozen major registries from
around the world can be accessed (http://
www.who.int/ictrp/about/en/). Finally, clin-
ical trial registries have been growing in
numbers internationally with governmental
mandates and support. For example,
the Indian government has established
the Clinical Trials Registry-India (http://
ctri.nic.in/Clinicaltrials/login.php), and
the European Community established the
EudraCT (https://eudract.ema.europa.eu/).
In sum, the development and adoption of
medical registries has largely been driven
by governmental action and financial
support, widespread requirements stipu-
lated by journal editors, and the support
of other large-scale nongovernmental
organizations.

Two years after their registration policy
went into effect, ICMJE concluded that the
results have been positive, “overwhelm-
ing,” and that the research community had
embraced trial registration (Laine et al.,
2007). However, there continues to be
substantial problems with compliance and
the completeness of data found in Clini-
calTrials.gov (Dickersin & Rennie, 2012).
For example, Earley, Lau, and Uhlig (2013)
found a failure to consistently and clearly
report an obviously important piece of
information for clinical trials—the number
of deaths. Dickersin and Rennie (2012)
argue that even if every trial was completely
registered the information would still be
lacking because not enough useful data
fields are required. Zarin et al. (2007) further
identified several issues in implementing
clinical trial registries including validating
trial entry data, ability to meet the needs of
a diverse user group, duplicate registration
entries, consistent defining and naming
conventions, coordination across different
registries including actual study results, and
maintaining confidentiality. A later study
(Zarin et al., 2011) found that many trial
sponsors are successfully meeting data entry
requirements of the FDAAA but that others
are struggling and that this is troubling given
the registry’s purpose and requirements.
They concluded that the usefulness of Clini-
calTrials.gov depends on the willingness
of researchers to provide accurate and
complete data in a timely manner. Dick-
ersin and Rennie (2012) reached another
slightly different conclusion from Zarin
et al. (2011) stating that success not only
depends on a culture of openness but also
on the energetic enforcement (presumably
enforcement of the legal and civil penalties
allowed under the FDAAA). An openness
culture is probably difficult to achieve given
the competitive and highly profitable world
of pharmaceuticals. Furthermore, a survey
performed in 2006 (before enactment of
FDAAA with civil penalties) found that
only 25% of academic researchers were
willing to disclose all items required by
ClinicalTrials.gov (Scherer & Trelle, 2008).
In addition, Prayle, Hurley, and Smyth
(2012) found that only 22% of trials
registered in ClinicalTrials.gov that were
completed in 2009 met the results reporting
requirement in the legislatively mandated
time frame. Thus, energetic enforcement
seems a wise though costly endeavor.
Table 1. Important Milestones in the Development and Widespread Adoption of Medical Intervention Registries

<table>
<thead>
<tr>
<th>Year</th>
<th>Milestone</th>
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<tbody>
<tr>
<td>1967</td>
<td>First computerized registry for trials of psychopharmacological agents developed by the U.S. National Institute of Mental Health.</td>
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<tr>
<td>1986</td>
<td>Simes publishes seminal article on publication bias that brings widespread acceptance of the value and importance of an international registry for all clinical trials.</td>
</tr>
<tr>
<td>1997</td>
<td>FDA Modernization Act (FDAMA) requires the NIH to establish a clinical trial databank.</td>
</tr>
<tr>
<td>2000</td>
<td>ClinicalTrials.gov launched.</td>
</tr>
<tr>
<td>2004</td>
<td>ICMJE requires registration of clinical trials as a condition as a precondition for publication.</td>
</tr>
<tr>
<td>2006</td>
<td>World Health Organization launches International Clinical Trials Registry Platform.</td>
</tr>
<tr>
<td>2007</td>
<td>FDA Amendment Act broadens registry requirements and establishes noncompliance penalties.</td>
</tr>
</tbody>
</table>

The dirty details of implementation and enforcement make even good legislative and research ideas fade away. The medical community has had the benefit of time, laws, governmental support, and funding (at levels unimaginable to I–O), and even then registry implementation has proven difficult.

It is important to identify the underlying characteristics of medical research that lent themselves to the widespread acknowledgment of the need for clinical trial registries. We believe that the main reason for the adoption of registries in the medical field is that medical research is directly applied and has life, death, and monetary consequences. These characteristics further result in intense public interest and concern. I–O psychological research, as it stands, is unaffected by these concerns. Given a lack of an immediate, “burning platform,” are we as a field willing to implement a large-scale solution such as registries or modify established reviewing practices so accurately critiqued by Kepes and McDaniel?

Unlike the medical community, we cannot expect governmental financial support and mandates. Thus, the full weight of such an endeavor would fall squarely on our shoulders. The changes our field makes to enhance the trustworthiness of findings will be, by necessity, incremental. Just as targeted specialty registries first took hold in medical research, any successful implementation would likely follow this path as well. For example, consider standardized testing. This research area is directly applied and has directly observable consequences. As a result, it has garnered widespread public attention. It already has some associated forms of government oversight, regulation, and laws that impact its practice. Last, but definitely not least, standardized testing involves substantial sums of money. All of these characteristics seem similar to the medical intervention research.

Modification of reviewing practice will require major adjustments in journal and associations’ missions to include exploratory work and replications—the new journal Academy of Management Discoveries seeks to do just that. It will also require the publication of replications in short-article format in our other mainstream journals and the serious acknowledgement of the problems created by ‘theory-relevant beliefs.’ But these will have to flow from editorial policies, and more importantly researcher, editor,
and reviewer practices. Simply put, our field will need to transform its collective agenda from a narrow focus on generating theory-relevant knowledge to generating rigorous and relevant knowledge, which may or may not support existing theory. With a strengthened relationship between literature and practice the conditions will be right for further consideration of widespread registry use.

References


