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Research in Translation: Getting Published

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United States
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In the past decade, the biomedical research community has devoted mounting attention—and funding—to translating basic laboratory observations into clinical reality. But even as bench-to-bedside approaches mature and prosper, translational research presents singular challenges for its practitioners. Translational research can be impeded by cumbersome regulatory requirements, difficulties obtaining samples, and challenges pinpointing the mechanisms underlying disease processes and therapeutic effects in human beings, whose genetics, environments, and behaviors cannot be tightly controlled. Therapeutic and diagnostic approaches that show promise in cell systems or animal models often come off the rails in human studies, and ethical and safety concerns can bog down the process interminably.

"It's a delicate, fragile process, and so few make it through," says Gregory Curfman, executive editor of *The New England Journal of Medicine*. "A good translational researcher is going to have to have a lot of patience and is going to have to deal with some failure. That's just the reality of it." It can be a bitter reality for early-career researchers because the slower the research, the slower the pace of publication.

Successfully executing and publishing high-quality translational research presents myriad hurdles. Yet editors of top-tier journals say they welcome innovative, rigorously performed, clinically relevant translational research more so now than ever.

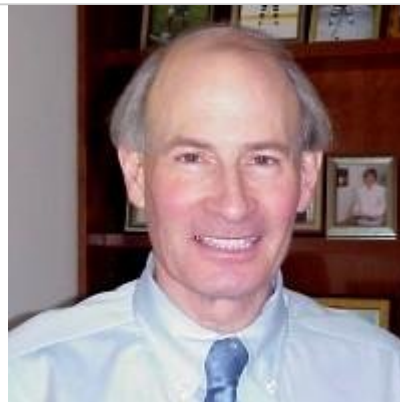
THE BEST-LAID PLANS

Many researchers begin to think about their publication prospects only after they've completed data collection and are ready to prepare a paper for review. But especially for translational scientists, peer review should start with the study design. Ask colleagues to

review your plans critically, either informally or through research-in-progress seminars, a fixture at many universities.

The planning stage is also the time to think strategically about collaborations. Some industry collaboration contracts—although not most—restrict researchers' freedom to reveal chemical descriptions of new compounds or share materials with other researchers. Because high-profile journals typically require such disclosures, such limitations can hobble your options before data collection has even begun.

The most serious mistake translational researchers commonly make, journal editors observe, is a study design that doesn't allow them to explain the processes underlying a disease outcome or therapeutic effect. "What we're not looking for is studies that are purely descriptive," says Heather Van Epps, executive editor of *The Journal of Experimental Medicine*. A study that merely describes differences in tissue pathology in different groups of patients, for example, probably won't even be sent out for review at her journal, she says.



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We're interested in papers that identify a new feature of a disease or a new mechanism by which disease is regulated and studies that investigate the mechanism behind a response to an experimental drug or vaccine that's already in use," Van Epps adds.

Don't despair: Editors do understand that pinning down mechanisms in humans is far trickier than it is in cell cultures or in experimental animals. "We want to battle the perception ... that [researchers] have to do as much in humans as they would in a mouse model, especially if the finding is important for a clinical application," says Ushma Neill, executive editor of *The Journal of Clinical Investigation*. "We certainly do acknowledge that there are limitations in doing research with human beings."

Likewise, editors recognize that moving from cell systems and animal models to human studies tends to be easier in some fields (for example, in immune system disorders) than in others (for example, in neurological disorders such as Alzheimer's disease or Parkinson's disease). "We try to be realistic about what we ask from the authors," and the journal's pages reflect that, says Juan López, chief editor of *Nature Medicine*.

Mechanistic thinking isn't the only critical component of a strong translational project. Equally important is experimental conditions that are applicable to human treatment. Removing a solid tumor from a mouse, for example, then sewing it onto the mouse's back and injecting an experimental drug directly into the tumor is too far removed from clinical reality, says one journal editor. Similarly, consider whether the duration of a laboratory experiment makes sense. If you're using mice to test a new drug for diabetes, a chronic disease, monitoring glucose levels for only a week after administering the drug will undermine your case for the drug's effectiveness.

Just as a weak study design can sabotage one's publication options, so can weak statistical inference. Solid statistical grounding is important for any scientist, but the numbers game is especially critical when conclusions hinge on correlational evidence, as human studies often do. "Even if the idea is very strong, if it falls down on the statistics it's unlikely to be accepted," Van Epps says. So translational researchers should engage a statistician to help ensure that their statistical bases are covered.

A PERSUASIVE SUBMISSION



Juan López

Once your study is complete and the data are analyzed, assemble the strongest possible submission package. Start by choosing the right journal. "A lot of people want to have a paper in a high-profile journal, and they submit to any of them without understanding what the different journals' criteria are," says López. He's seen submissions, he says, from people who evidently assume that *Nature Medicine* is a journal about medicines derived from plant extracts. It's easy enough to learn what different journals are looking for. Peruse author guidelines--usually available online--take explanations for rejections seriously, and seek out journal editors, who are usually willing to dispense presubmission advice.

In your submission, make a forceful case for the novelty and importance of your findings--but don't overhype results. Translational researchers are often tempted, especially in cover letters, to use terms such as "cure," says Paula Kiberstis, a senior editor at *Science*. "That doesn't necessarily impress the editors."

"There's a misconception that unless you tie it back to curing people or treating people that it won't be considered interesting for the journal," agrees Van Epps. "Authors are wiser to be a bit more circumspect and realistic."

Use your cover letter to suggest potential reviewers in your field. "One of the difficulties in publishing human studies is that a paper that gets sent to a mouse immunologist to review is probably not going to be very favorably reviewed," observes Van Epps. Although it's not appropriate to line up buddies to rubber-stamp your work, she says, editors welcome a carefully considered list of people with relevant expertise.

Finally, although the most compelling studies demonstrate that a new therapy or diagnostic marker is as good as or better than what's currently available, don't just file away null results--they may be publishable, even in top-tier journals. There is a lot to be learned by negative trials provided that the study was well-designed and had enough statistical power to convincingly rule out an intervention's effectiveness. In the end, Curfman argues, the most important thing is to tackle an original and compelling question, study it rigorously, and then "let the chips fall where they may."

Shepherding translational research to publication in high-impact journals "is not perfectly straightforward, but it's also not impossible," says López. "The paramount consideration is how original the work is. If people are coming up with a new signaling pathway or a new therapy, that's an excellent starting point. But that's where a lot of the papers that we see don't make the cut."

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Photos. Middle: courtesy, Gregory Curfman.

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