IN brief

$1.3 billion to translate

A £775 million ($1.3 billion) funding boost for National Health Service (NHS)–university partnerships to pursue translational research was announced in March. The UK's National Institute for Health Research (NIHR) will make the largest ever translational research—over five years. The grant scheme builds on the recently unveiled Model Industry Collaborative Research Agreement (MICRA) to broker research collaborations among universities, industry and the NHS. MICRA aims to help industry by identifying suitable clinicians and researchers for collaborations, as well as streamlining the negotiation and contracting process and ensuring that intellectual property can be assigned flexibly. Rob Winder of the BioIndustry Association in London said that even though biotech won't get funded directly by this scheme, it should lubricate their association with academia, help clinical trials start more quickly and otherwise speed up innovation. Industry is "very keen" on the new scheme, he added. According to Sally Davies, the UK's Chief Medical Officer and Director General of R&D at the Department of Health, the NIHR's researchers will play a key role in partnering with biotech companies. They already have a track record of liaising successfully with biotech in the fields of liver disease, regenerative medicine and DNA vaccines. The funding will prioritize cancer, heart disease and dementia. *Jennifer Rohn*

Pharma wins vaccine case

Vaccine makers breathed a sigh of relief after the US Supreme Court ruled on February 22 that the parents of Hannah Bruesewitz, who experienced seizures and developmental problems after receiving a Wyeth vaccine, did not have the right to sue the company in a state court. The Bruesewitzes claimed Hannah's problems began after she received the combined *Corynebacterium diphtheria* toxoid/*Clostridium tetani* toxoid/pertussis (DTP) vaccine against diphtheria, tetanus and whooping cough. They brought their petition to a Pennsylvania state court after their case was dismissed by a special Vaccine Court set up by a 1986 Act over fears at the time that lawsuits would force companies to stop making vaccines. The Act says suits cannot be filed against manufacturers if the injury was "unavoidable." In the *Bruesewitz v. Wyeth* case, the petitioners argued that Wyeth, now owned by New York–based Pfizer, could have put a vaccine with fewer side effects on the market earlier and thus their daughter's injury was avoidable (*Nat. Biotechnol.* **28**, 1228, 2010). But the Supreme Court's Justice Antonin Scalia dismissed these claims stating that "drug manufacturers often could trade a little less efficacy for a little more safety, but the safest design is not always the best one." Marion Burton, president of the American Academy of Pediatrics, applauded the decision saying, "The Supreme Court's ruling keeps manufacturers from abandoning the vaccine market." *Stephen Strauss*

Table 1 Selected companies pursuing pluripotent stem cell therapies

Company	Cell type	Potential clinical indication
Geron (Menlo Park, California)	Oligodendrocyte precursor cells differentiated from a hESC line	Spinal cord injury
Viacyte (formerly Novocell)	Pancreatic beta cell progenitors derived from human iPSCs	Diabetes mellitus
Life Technologies (Carlsbad, California)	Astrocyte precursor cells, differentiated from H9 human ESCs and injected into the cervical and lumbar spinal cord	Amyotrophic lateral sclerosis

is being addressed, in part, by testing human pluripotent stem cells or differentiated cells in nude mice that lack T cells to see whether they induce tumors. However, no one is sure how many animals or what cell numbers to test, or what constitutes a safe threshold or cut-off value, both Carpenter and Rao say. "After one year, the [transplants] are not causing any obvious toxic damage, and it's a big relief that we don't see teratomas," Rao says of the dopaminergic cells he and his colleagues are evaluating. "But I'm cautious about claiming that we'll never see [teratomas]."

Additionally, when retroviruses are used to generate iPSCs, they can "leave footprints, raising concerns about [insertional] mutagenesis," including that they might activate the *MYC* oncogene in such cells, says Kevin Eggan of the Harvard Stem Cell Institute in Boston. These concerns are prompting him and others to seek other reprogramming methods that avoid the use of retroviruses. Alternatives include non-integrating viral vectors, such as adenovirus or baculovirus adapted for expression in mammalian cells, exogenous plasmids, protein factors, chemically modified mRNA and even the use of small molecules or microRNAs that have a similar reprogramming effect. Most reprogramming approaches used currently yield "weird, partially induced pluripotent intermediate cells" that otherwise do not exist in nature, says Lee Rubin, also of the Harvard Stem Cell Institute. Some of those unusual cells "can spontaneously differentiate," he says. "There seem to be multiple paths open to these cells, and some of them maybe can be used therapeutically. I don't see why they couldn't be."

Another concern—the use of feeder cells to grow ESC and iPSC lines, which raised the possibility of xenotropic viruses and other contaminants entering the cells—can now be sidestepped, says Rao. It looks feasible to grow pluripotent stem cells without feeder cells on on chemically defined substrates, he explains. Tracking the origins of human cell lines and sublines is another critical issue. This is necessary to assure FDA regulators that those cells came from legitimate sources and are what they are supposed to be, including whether original donors consented fully to how they will be used. "We can adapt to xeno-free conditions, but it may be harder to adapt to these [requirements]," he says.

During iPSC product development, "early decisions can prove to be very important," says Eugene Brandon, director of Strategic Relations and Project Management at ViaCyte in San Diego. One example is ViaCyte's early move to evaluate suspension cultures. Surprisingly, "cells differentiate better [in suspension] than in small culture [plates] with adherent surfaces," he says. This early work on scale-up conditions took the equivalent of about five full-time investigators two years to develop, he notes. The company, which is developing cells to treat type-1 diabetes, plans to deliver either pancreatic progenitor or insulin-producing beta cells by means of a device the "size of a dollar bill," he adds. This "promising product—pre-Investigational New Drug in the not-distant future"—comes under jurisdiction of the FDA Center for Biologics Evaluation and Research, with co-review by the Center for Devices and Radiologic Health.

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IN their words

"They all are throwing the baby out with the bathwater, totally changing what they call R&D into S&D, you know, Search and Development." Sofinnova's Antoine Papiernik maintains that the venture industry should be delighted at big pharma's changing strategy because biotech can deliver the innovation they seek (*Xconomy*, 30 March 2011).

"Our job is [...] to create conditions for formation of powerful biotech sector in Russia." Prime minister Vladimir Putin told oil and telecoms tycoons to focus on biotech's growth potential, ordering a plan for Russia to reach a 5% share in the global biotech market by 2020, up from the current 0.2% (*Reuters*, 1 April 2011).