

Call for collaboration in dementia research

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Dementia is devastating for patients and their caregivers, but the high risks associated with traditional research and development methods are stalling progress to a cure.

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Business as usual is not an option in the global fight against dementia, urged experts at a legacy event held Sept. 11–12 in Ottawa. They called for collaboration and regulatory flexibility, as well as financial incentives for researchers and drugs companies, to sustain long-term investments towards finding a cure.

Traditional research and development hasn't delivered results, and may not show progress before health systems are overwhelmed, World Dementia Envoy Dennis Gillings told delegates to the Canada–France Global Dementia

Legacy Event. “There are 44 million people with dementia around the world and yet just three drugs have been developed in over 15 years.”

Part of the problem is how much is still unknown about the disease. “Dementia is probably tens of diseases or more, and the solution may be a combination or multiple therapies,” said Gillings. “That means the research effort is very substantial and some therapies won't show their full merits until the synergies with others have been discovered.”

In particular, “we need more knowledge about targets in the brain that the pharmaceutical industry can build drugs to stimulate.” But identifying those targets comes under the rubric of basic neuroscience, and attrition is high in discovery and early development.

Mounting evidence also suggests that changes in the brains of people with Alzheimer's disease can begin decades before symptoms appear. One explanation for recent Phase-3 trial failures is that patients took the drugs too late in the disease process, when they had already suffered significant brain cell death. As a result, 2013 saw a shift towards trials with patients in earlier stages.

More broadly, however, “there was a sense that industry was starting to walk away from this question,” Federal Health Minister Rona Ambrose told reporters at the event.

Panelists agreed that collaboration was a first step to lowering the investment risks associated with dementia research. In industry, that starts with companies pooling data to reduce inefficiencies and learn from each others' mistakes, said Michel Goldman, executive director of the European Union's Innovative Medicines Initiative.

For example, “five companies developing new antipsychotics that pooled their data ... demonstrated you can reduce by 40% the number of patients you have to enrol in a trial to demonstrate drug efficacy.”

Others suggested collaboration to standardize contracts and regulatory requirements between companies, academia and governments, and across international borders.

Panelists also proposed that both industry and academia require incentives from government and possibly health charities to engage in the kind of long-term exploratory research required in the case of dementia.

For governments, “where in some cases there are trillions of dollars in costs at stake,” the business case is clear, said Andrea Ponti, partner in GHO Capital Partners, a UK healthcare-focused private equity firm. Possible incentives could include tax breaks for collaborating with other companies.

Still others argued that dementia drugs may merit a special regulatory category with expedited review, as in certain cases with medicines for HIV, oncology and orphan diseases.

This suggestion drew ire, however, from health regulators in the room. “In this era of teamwork, we don't want the umpire to be an advocate,” said Robert Cushman, director general of the Biologics & Genetic Therapies Directorate at Health Canada.

However, Cushman agreed that international collaboration to review drugs might ease the burden on smaller regulators. “We have to survey the same waterfront, the same number of medicines and the same complications that the US Food and Drug Agency does with 10% of their budget and size.”

Some 200 delegates from G7 countries and major international organizations attended the Canada–France Dementia Legacy Event. It's the second in a series of four events stemming from the Summit on Dementia held in London, England, in December 2013. The next events will take place in Japan in fall 2014 and the United States in winter 2015, with a wrap-up session in March 2015.

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