21st century cures emerge as 20th century science matures

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Credit: Bentley University

Most of the new drugs approved by the FDA since 2010 arose from basic scientific research that was initiated in the 1970s or 1980s, a new study from Bentley University has found. The analysis shows that development of new targeted and biological therapeutics rest on the maturation of basic science over decades. The research, published today

in the journal *PLOS One*, appears as scientists are increasingly concerned about federal support for basic biomedical research.

The *PLOS One* article, titled "Timelines of translational science: From technology initiation to FDA approval," uses an analytical model for the growth of basic research to examine the relationship between the progress of research and approval of new drugs based on this work. The study from Bentley's Center for Integration of Science and Industry examined all of the drugs approved by the FDA from 2010-2014. The analysis shows that basic biomedical research on drug targets follows predictable patterns of growth and maturation, and that the ability to successfully translate this science into new therapeutics depends on first achieving a certain level of maturation.

"While we celebrate the 'a ha' moment of scientific discovery and invention, such moments are only the point of initiation for the basic research required to develop new drugs," said Dr. Laura McNamee, the lead author of the paper and a research associate in Bentley's Center for Integration of Science and Industry. "Our analysis shows that very few targeted or biological therapeutics emerge from this basic research until it becomes established."

The paper published showed that the efficiency of drug development improved significantly when the enabling science passed an established point defined by the analytical model. No targeted or biological products were approved before this point, and clinical development of approved products was three years shorter for products that entered clinical trial trials after this point.

"Translational medicine remains a largely empirical process, and we are only beginning to apply the theories and analytical tools of systems engineering and technology management to improve the efficiency of translational science," said Dr. Fred Ledley, founding director of the

center and a co-author of the paper. "Modeling the process of translational science, it is clear that greater emphasis needs to be placed on expediting the growth of basic biomedical research to improve the efficiency, timelines, and cost of bringing new cures to market."

More information: Laura M. McNamee et al, Timelines of translational science: From technology initiation to FDA approval, *PLOS ONE* (2017). DOI: 10.1371/journal.pone.0177371

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