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# Are there ways to support new drug innovations?

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**There are a lot of discussions on going about reasons for the decrease of new drug innovations. It is postulated that one main reason might be that the costs for developing a new drug are increasing since years. Another reason might also be that it is getting more and more difficult to recruit the appropriate number of subjects. Just investing more money into clinical trial programmes will very likely not increase the number of new drug innovations or even approvals. What would be required is a more holistic approach of the drug life cycle using and implementing faster new technologies and leaner regulations. Also a shift of focus, for example in regards to publication of failed studies, will be required. Detailed analysis and presentation why studies have failed, meaning identifying which were the reasons behind and presenting such information in due time, is currently not standard. Therefore, lessons-learned cannot be done in a timely manner. Despite the waste of money, there is also a waste of ethical resources, as patients who are participating in a trial which fails, had a higher safety risk than patients on standard treatment. Thus, it is important to identify fast and efficient ways of conducting drug development without increasing risk in patient safety or data quality. To establish this, the regulations should allow better usage of electronic devices and software, exchange of data, usage of more computerised models and agile project management. Data regarding reasons for failure of clinical trials and decrease in new drugs developments can be collected and analyze using data science with a streamlined process via collection of failure data, following organization of data (what is needed and what not), analysis of data using tools (R, SAS, SPSS, Advanced Excel and Python) and open report of results.**

## Biography

Anika Staack has completed her Master of Science (Biology) from Marburg University. She is currently working as EU-QPPV for a pharmaceutical company. In total of more than 14 years' experience within drug safety/pharmacovigilance she collected experience with the European and FDA regulations, safety databases, post-marketing studies, inspections, especially risk management and safety evaluation. Her main research is focusing on the impact of regulations on drug life-cycle and effectiveness on health care systems.

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