



## FACT SHEET

### CONTACT:

Jeremy Glunt

Association of Clinical Research Professionals

+1.703.258.3506 or [media@acrpnet.org](mailto:media@acrpnet.org)

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Association of Clinical  
Research Professionals

#### ADDRESS

99 Canal Center Plaza  
Suite 200  
Alexandria, VA 22314

#### PHONE & FAX

703 254 8100  
703 254 8101

#### EMAIL & WEB

[office@acrpnet.org](mailto:office@acrpnet.org)  
[acrpnet.org](http://acrpnet.org)

## KEY FACTS ABOUT THE CLINICAL RESEARCH INDUSTRY

The U.S. leads the world in both overall clinical trial activity and early stage clinical research. – **PhRMA**

The development of a drug can take a very long time, and sometimes even when the drug reaches the clinical trial stage, it does not become an approved treatment. About 1 out of every 5 drugs in the clinical trial process are submitted to the Food and Drug Administration (FDA) for approval. However, of the drugs that are submitted for approval, there is a 93.2% chance it will be approved. –

***Tufts Center for the Study of Drug Development***

The number of new drugs approved in the United States fell in 2013 compared to the previous year as fewer applications were filed, though several products for hard-to-treat diseases were approved in record time. 27 new drugs were approved in 2013, down from a banner year in 2012, which saw 39 drugs approved for the greatest number since 1997. – **FDA**

Time to market for a new drug is now averaging 12 years, ranging from 10-15 years and less than 20% of trials are actually completed on time. – ***Alliance for Clinical Research Excellence and Safety (ACRES)***

The average cost of developing new medicines rose 18 percent to \$1.3 billion between 2010 and 2013. Yet the average peak sales forecast for each new drug dropped 43 percent to \$466 million in 2013 from \$816 million in 2010 – ***Deloitte and Thomson Reuters***

Of the \$70 billion the industry spends every year, 30% is wasted through inefficiency and redundancy—every year over \$20 billion is squandered, while the cost of bringing a new drug to market soars, current estimates ranging from \$1.5-\$5.5 billion. – **ACRES**

Rising research and development expenditure and increased outsourcing are expected to continue fueling steady growth of the global CRO market, which is



poised to grow from \$23-\$25 billion to more than \$30 billion by 2018. – **Bank of America Merrill Lynch**

Budgeting and contracting remains the top cause of study delay. Of 950 participating investigative sites, 49% of respondents pegged contract and budget negotiation and approval as a key factor in study delay, more than any other activity, edging out patient recruitment, which scored 41%. – **CenterWatch Survey**

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