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Record 59 new US drugs launched in 2018: IQVIA

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A third of the new drugs identified as innovative therapies with novel mechanisms of action different from existing therapies

Ongoing changes in the clinical development process led to a record number of drug approvals in 2018, with 59 novel treatments reaching patients in the United States alone. During the next five years, trial productivity will be heavily influenced by key trends, including wider use of biomarkers, pre-screened patient pools, regulatory shifts and application of artificial intelligence and predictive analytics.

To examine historical and future clinical trial productivity trends across therapy areas a new report from the IQVIA Institute for Human Data science titled, The Changing Landscape of Research and Development: Innovation, Drivers of Change, and Evolution of Clinical Trial Productivity puts forth a proprietary Clinical Development Productivity Index that reflects changes in trial complexity, success and duration.

Using this index, the report takes a 10-year historical view of these metrics and recasts the data with a future perspective that identifies critical productivity changes expected through 2023. IQVIA experts shed light on those productivity shifts using the proprietary IQVIA Clinical Development Trends Impact Assessment, identifying the quantitative impact of the eight key trends driving change in clinical development at a therapyarea level. Those drivers are:

- Digital health technologies to enable the capture of drug efficacy and safety data remotely, which can improve patient safety, enable virtual trial formats and ease site work burden.
- Patient-reported outcomes that will shed new light on patient experience and drug efficacy and safety outside the clinical setting and lead to accelerated trial times as endpoints shift.
- Real-world data to optimize trial design, speed investigator and site selection, and enable new trial designs by acting as virtual control arms and supporting pragmatic, adaptive and RWE registry trials.
- Predictive analytics and artificial intelligence to identify new clinical hypotheses, reduce trial design risks and speed enrollment by identifying protocol-ready patients.
- Shifts in types of drugs tested, for instance, to targeted therapies and next-generation biotherapeutics that improve

efficacy and success rates and have accelerated development timelines but require longer-term patient follow-up.

- Biomarker testing availability to help narrow patient populations to those more likely to see effect, resulting in improvements in efficacy, safety and success.
- Regulatory landscape changes that will encourage the adoption of precision medicine approaches, novel trial designs and endpoints while providing means for accelerated drug approvals and regulatory success.
- Pools of pre-screened patients and direct-to-patient recruitment, which will facilitate enhanced trial enrollment, shortened trial duration and faster market availability.

“As advances in science, technology and data gradually find application within clinical development, the length of time that trials take to complete, the resources required due to trial complexity and likelihood of trial success are all shifting, with impacts varying by therapy area,” said Murray Aitken, IQVIA senior vice president and executive director of the IQVIA Institute for Human Data Science. “Our study assesses the current activity within research and development, the productivity levels of the clinical development process and how key trial trends will transform clinical development over the next five years.”