2015 YEAR IN REVIEW

DRUG DEVELOPMENT & MANUFACTURING

HILLARY CLINTON PROPOSES CAP ON PATIENTS' DRUG COSTS AS THE 2016 PRESIDENTIAL RACE HEATS UP. NICE REJECTS DRUGS ON BASIS OF PRICE AND COST-EFFECTIVENESS
FDA APPROVES FIRST BIOSIMILAR PRODUCT IN THE UNITED STATES. ZARXIO. THE TPP AGREEMENT NEGOTIATES TERMS FOR BIOLOGIC EXCLUSIVITY
TRENDS IN CLINICAL TRIAL DESIGN INCLUDE: INTEGRATION BETWEEN ECLINICAL TECHNOLOGIES, PATIENT-CENTRIC APPROACHES, AND REAL-WORLD DATA
THE TOP FIVE PUBLIC CROs' MARKET CAP GROWS 41% IN 2015. AND THE TOP FIVE PUBLIC CMOs SEE 47% GROWTH, DESPITE SLUGGISH MARKET
LABCORP ACQUIRES COVANCE FOR $6.1 BILLION. ICON TO USE IBM'S WATSON FOR CLINICAL TRIAL FEASIBILITY
SPONSORS AND CROS USE FORMAL PREFERRED PROVIDER AGREEMENTS EVEN MORE IN 2015

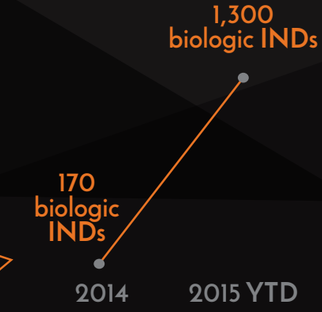
BIOLOGICS

Sandoz's Zarxio is the first biosimilar approved in the U.S. (March). Zarxio is the drug filgrastim, originally Amgen's Neupogen.

Under the Trans-Pacific Partnership Agreement, countries have two options for biologic exclusivity:

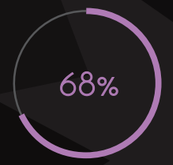
- eight years of full exclusivity
- or five years of data exclusivity plus an additional three years of semi-exclusivity.

"In 2014, we had a little more than 170 original INDs [investigational new drugs]," Steven Kozlowski, M.D. director of the FDA's Office of Biotechnology Products said. There are currently more than 1,300 active biologic INDs.

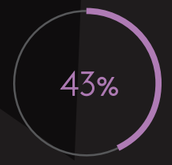


PREFERRED PROVIDERS

Formal preferred provider agreements continue to grow in popularity, particularly between sponsors and CROs.



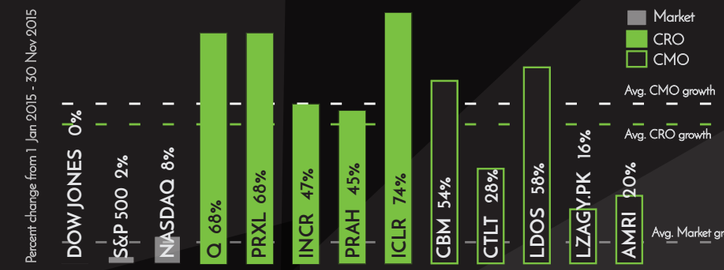
of sponsors have formal preferred provider agreements with **CROs**



of sponsors have formal preferred provider agreements with **CMOs**

FINANCIAL GROWTH

and the top five public CMOs saw 47% growth.



PARTNERSHIPS & MERGERS

M&A made ISR's year in review list yet again, and will likely play a role in 2016 as well. Some of the notable partnerships include:

DRUG PRICING

After Turing Pharmaceuticals raised a drug price over 5,000% in a single day, drug prices were the focus of much debate. The UK's National Institute for Health and Care Excellence (NICE) also rejected drugs on the basis of price.

>> look for drug pricing to play a role in the 2016 presidential debates

NICE rejected Astellas' prostate cancer drug Xtandi due to "many uncertainties" with the data, including cost-effectiveness. (June 2015)

Turing Pharmaceuticals, a start-up run by a former hedge fund manager, acquired Daraprim and raised the price from $13.50 to $750 per tablet, drawing criticism from the media. (Aug. 2015)

NICE rejected AstraZeneca's ovarian cancer drug, Lynparza, saying the price "is too high for the benefit it may provide." (Aug. 2015)

NICE rejected Roche's Kadcyla on the NHS because the price of the breast cancer therapy "remains too high." (Nov. 2015)

TRIAL DESIGN

As of December 1, there have been 203,788 registered studies this year. Trends include:

Reliance on eClinical technologies, most importantly integration among these technologies.

A patient-centric approach, including protocol design and direct-to-patient recruitment.

More emphasis on real-world data for patient recruitment trial design, and reimbursement decisions.

Growth of Clinical IT to better identify patterns in clinical operations functions.

SOURCES: ISR REPORTS / ISR'S CRO QUALITY BENCHMARKING REPORTS / ISR'S FILL FINISH CONTRACT MANUFACTURING QUALITY BENCHMARKING (2016) / THE NEW YORK TIMES / PMLIVE.COM / THE TELEGRAPH / PHARMAPRO.COM / LIFE SCIENCE LEADER

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