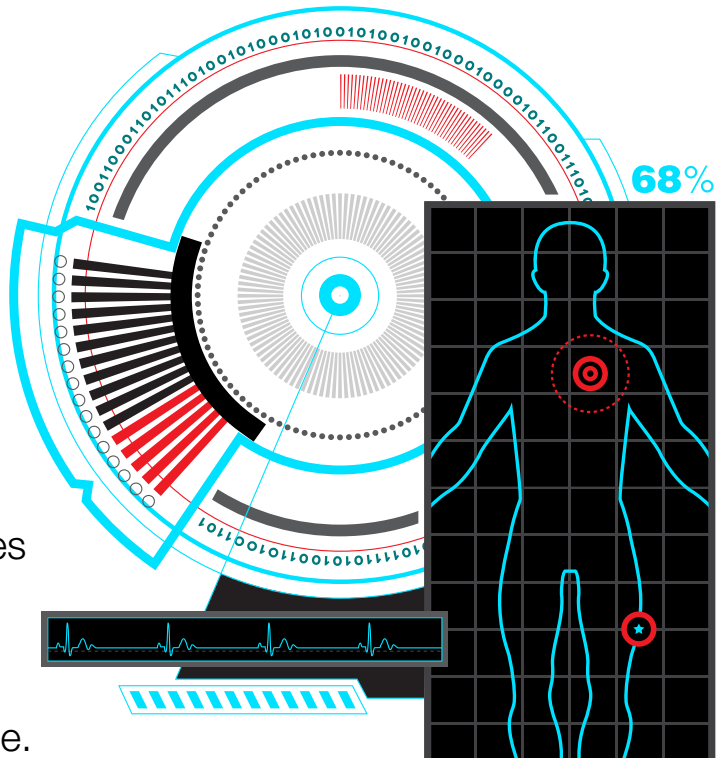
CLARKSTON CONSULTING

2015 Biotech Trends

As the global population grows increasingly focused on quality of life, many are also taking an active role in monitoring and improving their own health. Simultaneously, therapy advances are driving biotechs closer to the patient. These trends will inevitably create a paradigm shift in the interaction between patient and innovator. As such, investment in technologies that enable large-scale data analysis and more personalized therapies will strengthen. Additionally, cost pressures from payers and aggressive, targeted M&A activity will force biotechs to optimize their operations to remain competitive in an evolving marketplace.



01 PERSONALIZED MEDICINE

President Obama's announcement of the Precision Medicine Initiative[1] this year emphasizes the importance of employing patient data to develop personalized medical solutions.

Personalized Evidence Based Medicine (EBM) uses diagnostic testing on patients to analyze genetic, cellular or molecular data to identify biomarkers, predict future illnesses and proactively treat them.

A growing number of companies are leveraging personalized therapies, such as t-cell based personalized immunotherapies and oncogenomics, to treat conditions in a customized way. However, this shift may present challenges with intellectual property rights, reimbursement policies and patient privacy.

02 REGENERATIVE MEDICINE

With FDA and global regulatory agencies emphasizing stringent proof of clinical efficacy and innovation, companies exploring regenerative medicine are experiencing complicated and, in many cases, unclear regulatory pathways.

Organovo, however, recently valued at $500 million,[2] has achieved FDA approval and reached market commercialization with their 3D-printed human liver tissue preclinical drug assay. Biotechs investing in regenerative medicine (whether cell modifying, allogeneic, or autologous treatments) should evaluate factors such as: patent risks, regulatory pathways and dialog, reproducible GMPs, necessary yields and manufacturing scale, handling and storage approaches, and marketing & payer strategies.

03 SOCIAL MEDIA

Patients use social media for treatment information, to seek usage advice, and to provide feedback on therapy experiences. This begs the attention of biotechs, investors[3] and regulators. As such, the FDA has published industry guidelines for corporate social media engagement.

How biotechs interact with patients on social platforms will demand both an offensive and defensive strategy. Roche and Regeneron have published social media policies to mitigate the likelihood of noncompliance, the effects of which Chimerix has already exemplified. In 2015, as social media continues to impact public perception, biotechs will need to develop concrete guidelines for how they will engage in social media.

04 | MERGERS & AQUISITIONS

With the goal of increasing long-term growth prospects and decreasing costs, a visible driver of M&A activity in the biotech space in 2014 was tax inversion.

While mergers and acquisitions will be a leading trend in the biotechnology space through 2015, M&A activity is expected to be more about aggressive pipeline expansion and market capitalization.

Starting off the year, Shire bought NPS Pharma and Roche made deals with both Foundation Medicine and Trophos. Additionally, Pfizer bought Hospira for $17B, which is considered only the tip of the iceberg in Pfizer's deal-making for 2015.

05 | PAYER PRESSURES

To combat soaring drug prices, Express Scripts, the largest prescription drug plan manager in the U.S., dropped 44 brand name drugs from their formulary last year. This list will expand to 66 in 2015 and grow longer in 2016. Additionally, CVS Health will exclude 95 prescription products from reimbursement in 2015, up from 72 in 2014.[4] While they estimate annual savings in the billions, this will reduce biotech profits, with mid-sized companies with broad portfolios (specifically those including me-too products) taking the brunt.

To offset this, biotechs should design clinical trials with components that will continuously monitor therapeutic value in order to build a business case for payers.

06 | DIGITAL HEALTH

Patients are becoming more involved in tracking, managing, and improving their health through mobile health applications, wearable devices and a plethora of online health resources. The mainstream adoption of Electronic Health Record (EHR) systems also demonstrates providers' move to digital.[5,6]

Innovative biotechs will push the traditional boundaries of clinical data collection by gathering and analyzing data from initial diagnosis through long-term treatment. Not only will they use this data to measure quality of life, but also to improve upon existing therapies – or to develop entirely new ones. FDA's plan to bolster patient privacy and data security regulations,[7] however, may further complicate the use of such information.

Interested in Reading More?

- 2015 Life Sciences Trends Report
- The Growth of Regenerative Medicine
- The Impact of 3D Bioprinting on the Life Sciences Industry

Look for more detailed insights on these six trends throughout 2015.

References

1, 7. The White House, Office of the Press Secretary. Fact Sheet: President Obama's Precision Medicine Initiative. January 30, 2015.

2. Yahoo! Finance. Organovo Holdings, Inc.

3. Chen, Caroline. Hedge Funds Listen In on Patient Chats for Pharma Bets. Bloomberg. October 2, 2014.

4. Beasley, Deena. Exclusive: Express Scripts presses for more drug savings with coverage list. December 23, 2014.

5. The Office of the National Coordinator for Health Information Technology. Joint Health IT Policy and Standards Committee Meeting: Data Update. February 10, 2015.

6. Hirsch, Maria Durben. Survey: Doc HER adoption leveling off. FierceEMR. February 9, 2015.

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