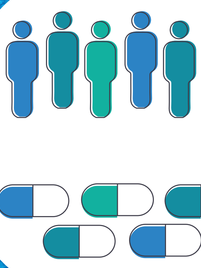
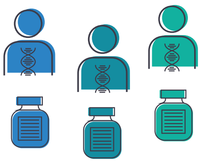
FIVE TRENDS IN PHARMA IN 2019

1. TRANSPARENCY IN CLINICAL DATA REPORTING



This year, the 2018 Edelman Trust Barometer showed consumer trust in the pharmaceutical industry hit a new low to a score of 38%, marking the industry as the least trusted of the 15 industries tracked by Edelman. Patients, payers, and politicians carry an even more critical view on the industry and are increasingly expecting and demanding transparency, so regulators are following suit with regulatory levers to drive greater visibility across the industry - including clinical trials. The FDA released a draft guidance in September 2018 introducing penalties for entities or responsible parties that fail to register clinical trials or report clinical trial data in a timely fashion. Moving forward, drug makers and clinical research and development organizations must embed transparency into each step of the clinical process. As the industry shifts towards greater visibility for all stakeholders, companies will be well-positioned by beginning this change management effort now.

2. WHAT'S NEXT FOR PERSONALIZED MEDICINE?



2018 was a banner year in personalized medicine, representing a dynamic shift in the way drugs are developed and administered – particularly in oncology. Looking to 2019, it's readily evident that we're just scratching the surface of personalized medicine's potential both therapeutically and commercially. With few approved treatments on the market, companies with developed or developing CAR-T treatments are realizing the difficulties in commercializing the products due to high costs to the patient and insurers. Furthermore, while innovation in the space has been tremendous, we're only beginning to understand the hefty side effects the treatments can carry. Regardless, CAR-T treatments and other personalized and precision medicines remain a promising evolution for the industry. As we move into 2019, innovators in this space must keep a critical, laser focus to managing the end cost to the patient and collaborating with payers early.

3. DEMOCRATIZING INNOVATION ACROSS R&D

With the advent of personalized and precision medicines, scientific and therapeutic innovation in pharma has entered a renaissance of sorts. But, even with breakthrough therapies in drug development, the business of R&D is entering dire straits as we look to 2019. Over the past 20 years, studies have shown an alarmingly consistent decline in returns on R&D investment across the industry – so much so that industry analysts are predicting 0% ROI on pharma R&D within just a few years. There's not one strategy that will solve this complex issue so industry leaders must be even more meticulous in their assessment of current R&D practices and systems. Leveraging new technologies and capabilities will certainly support R&D transformation but solving the R&D crisis will require a deeper, more intensive assessment of the intrinsic traits, long-standing processes, and fundamental culture of modern R&D organizations.

4. DATA INTEGRITY – CHALLENGING PHARMA ACROSS THE GLOBE

Data integrity is nothing new in pharma – while its focus has shifted over time, it's a concept that any quality or regulatory professional has immersed themselves in over the course of their career. What has changed in recent years is the continuously growing emphasis by the FDA and other regulatory bodies on data integrity. The multilayered task of addressing data integrity within the business is further compounded by two key trends – 1) pharma is embracing digital tools and capabilities, thus collecting and storing more data points, and 2) with a shift to personalized, "living" medicine, even more data must be collected, monitored, and reported as the treatments are particularly sensitive to numerous factors, e.g. fluctuations in temperature. While digital tools can help organizations better manage data integrity, a culture of quality has been closely linked to improved outcomes relative to data integrity. Pharmaceutical organizations of any size will need to focus on those core tenets of a quality culture moving forward to sustainably navigate the more scrutinous regulatory environment.

5. CONTINUING THE DRUG PRICING CONVERSATION

In an industry already beset with headlines, legislators, and patients admonishing prescription drug costs, the high price tag associated with personalized medicine will continue to put drug pricing under scrutiny. While 2018 famously saw many manufacturers avoid price increases, CMS still projects an increase in prescription medicine's portion of overall health spend. In recent months, there has been a regulatory and political push to require that manufacturers publicize drug prices on TV advertisements and commercials. In the near future, politicians and regulators are clearly aiming to make big waves when it comes to drug pricing. Moving into and through 2019, pharmaceutical executives should continue to emphasize transparency and collaboration when it comes to drug pricing.

CLARKSTON CONSULTING