

Business services for

# LIFE SCIENCES



Accelerating Your Business

## Life sciences industry

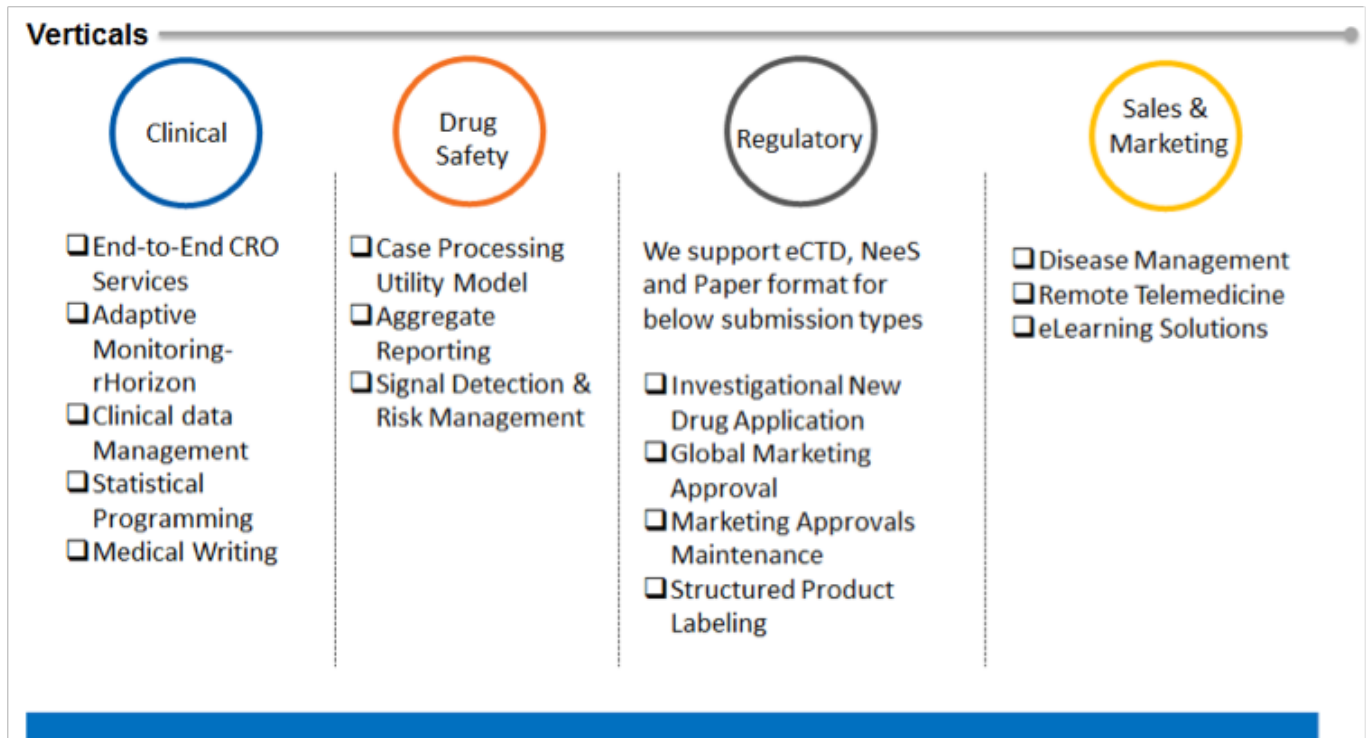
Over the last decade, the pharmaceutical industry has experienced a steep decline in R&D productivity. Even though the R&D spend has tripled, the number of new drugs approved by FDA have been reduced to 30%, thus increasing the pressure on pharmaceutical industry to bring in greater efficiency in every process. Life Sciences companies are looking for comprehensive solutions at every stage of the product development life cycle, rather than just the simple outsourcing models, reducing the risks and costs.



## Life Sciences Business Services

HCL offers a wide range of business services to support the Life Sciences industry across the value chain adding value to customers. HCL provides innovative and industry leading solutions in the R&D space that brings huge savings to the pharmaceutical industry. HCL engages with industry through unique models such as BPaaS and Utility models. HCL with its deep domain expertise and industry knowledge provides its clients the competitive edge to stay ahead in the race.

HCL's Life Sciences business services offerings are categorized into four broad areas, Clinical, Drug Safety, Regulatory, and Sales & Marketing



## Clinical

HCL offers a range of services to guide pharmaceutical, biotechnology, and medical device companies to get their new products to market sooner. HCL stands for quality that meets all of the requirements of its customers in a professional way that is free of ethical, regulatory, and scientific deficiencies. For HCL, quality is embedded in every aspect of the business. HCL's Clinical services include:

- End-to-End CRO Services
- Remote Central Monitoring
- Risk Based Monitoring - rHorizon
- Clinical Data Management
- Biostatistics
- Medical Writing





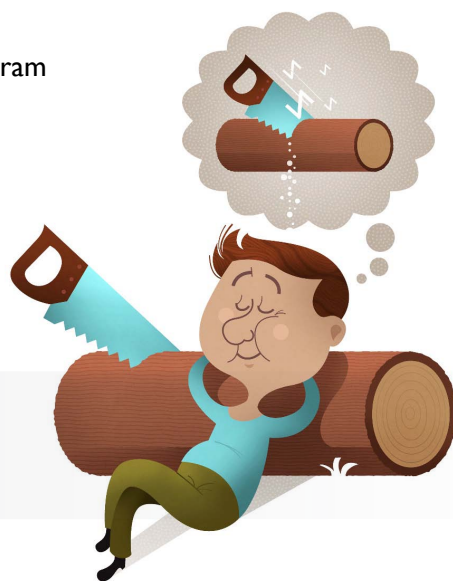
## Drug Safety

HCL is a leading Drug Safety services provider with review and reconciliation of Safety and Serious Adverse Event Data. Current progress in Drug Safety is marked by increasing use of databases and by attempts to make the process more proactive and organized. These changes are emphasized by the recent guidance documents for industry, by both EMEA and FDA, on safety planning and risk management.

HCL's focus is not just to enhance the operational excellence elements, but in building a robust PV organization, that can cater to the complex regulatory requirements, and quickly respond, to the changing needs, in a global environment, especially in the emerging markets.

HCL's integrated approach to the sponsor's drug safety operations includes the following:

- AE Case Processing- an Output Based Utility Pricing Program
- Aggregate Reporting
- Signal Detection & Risk Management



## Regulatory

HCL is a competent healthcare regulatory services provider for clients across the globe. With never ending emerging changes in regulations and guidelines, launching drugs in multiple countries and growing competitive challenges, pharmaceutical, biotechnology and medical device companies of all sizes, must find ways to reduce costs and turnaround times, for quicker regulatory submissions. HCL's innovative relationship and global delivery models help to achieve this objective of faster more cost efficient and timely submissions. HCL delivers high quality and best practices based significant value solutions. It leverages its global resources and a worldwide technology infrastructure, to achieve a coordinated team effort to deliver this value.

HCL Life-Science has capability to support eCTD, NeeS and Paper format submission for the below submission types:

- Investigational New Drug Application Submissions
- Global Marketing Approval Submission
- Submission for Maintenance of Marketing Approvals
- Structured Product Labeling



## Sales & Marketing

Doctors, pharmacists and payers believe in keeping the patient dependent on prescriptions only. Patients like depending on these prescriptions considering best health results. As the treatment can vary from days to months it is important for Doctors and Pharmacists to understand the connection between a patient and the prescribed medicine. While considering the urgency and importance of patient health HCL has continued its relationship with its existing pharmaceutical clients to inform patients about their treatment and walk them through their health plans prepared by HCL clinical specialists.

HCL provides a bridge between patients and physicians by educating them on all supportive activities and reports which in return help HCL take measurable continuous improvement steps. HCL adheres to all applicable laws and regulations as well as to industry standards. In order to maintain the highest degree of standards and quality HCL make sure that our specialists are trained on medical activities related to different therapeutic areas on a continuous basis.



HCL provides extensive post-marketing support services such as:

- Disease Management- Patient Support Programs Outbound Calling by Health Care Professionals for better Compliance, Adherence and Outcomes
- Remote Telemedicine by Health Care Professionals
- eLearning Solutions for Sales Reps and in Clinical Trials
- zCMO- Socialytics –Listening Post for the Patients Independent Sentiments about various drugs
- Inbound and Outbound Call Centers for supporting Product Launches, Product or Services Access Marketing, Clinical Trials Support, SFA Support for Sales Reps.
- Virtual Marketing Representatives- Telemarketing to Prescribers using the latest technology
- Big Data Analytics such as Socialytics- Safety AE Monitoring