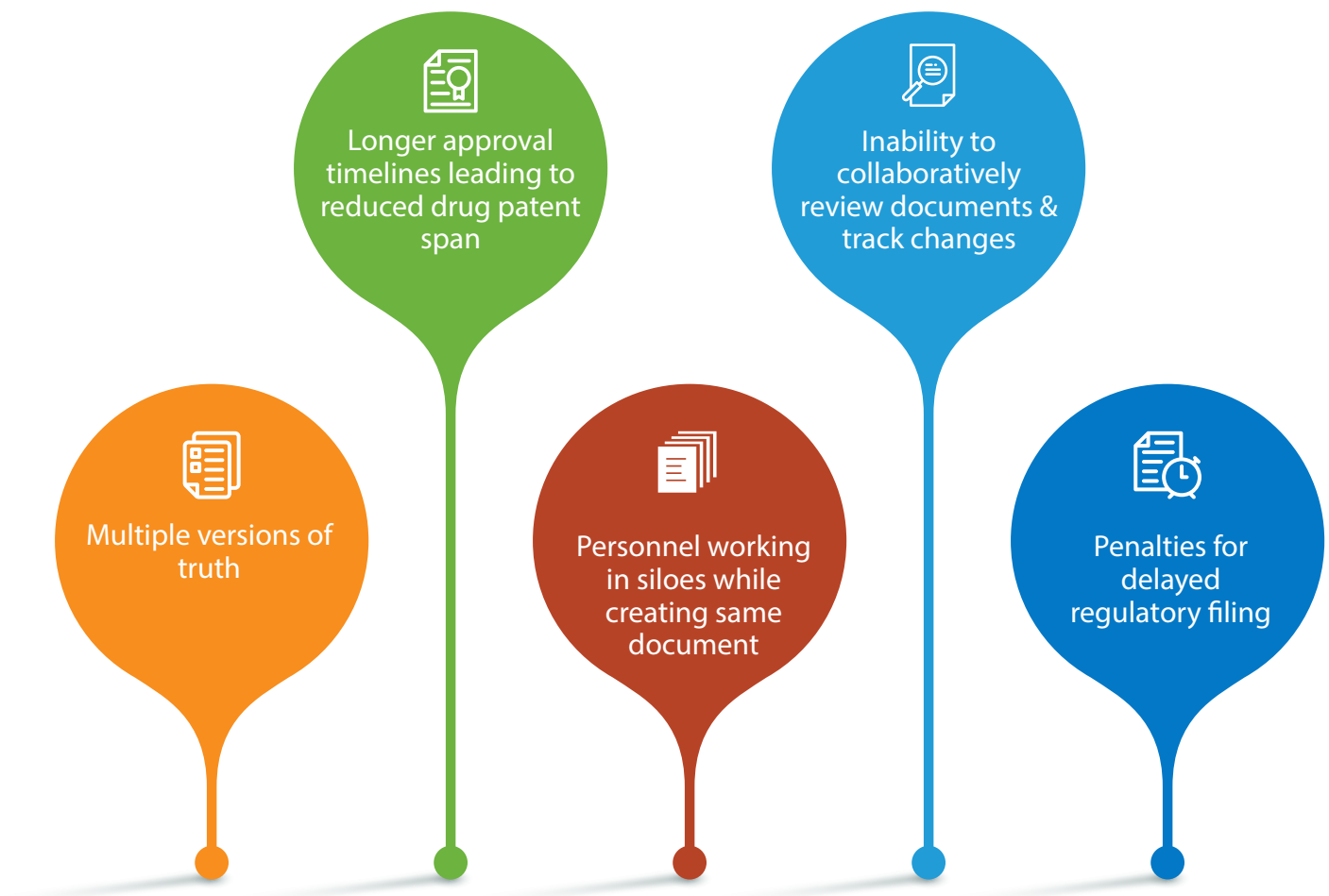
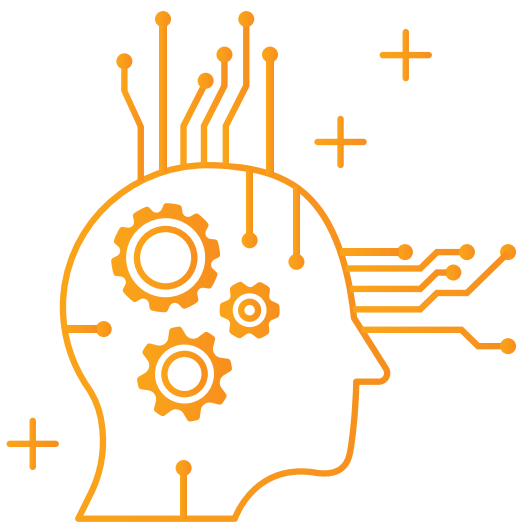
R&D CONTENT AUTO-GENERATION

Industry Need

Pharma companies typically spend about 25% of the estimated $1 billion drug development cost on creating documentation, regulatory filing and updates. Traditionally, pharma companies onboard a large medical writing team to manually create these documents. This business process is cost prohibitive and delays time-to-market because of which pharma loses the chance to monetize its patents fully. Apart from monetary aspects, creating content manually creates challenges including:



Infosys Solution



This Infosys solution delivers artificial intelligence based auto-generated content, capabilities such as collaborative and qualitative review, coupled with workflow management to bring transparency, improve efficiency and possible savings of ~$20 million per year for a pharma company. The solution leverages the power of the Infosys AI and automation platform, and adheres to industry standards like CDISC, ICH E3 guidelines as well as cross-industry initiatives like Common Protocol Template from TransCelerate.

Outcomes

Clinical Development, Regulatory Affairs, Safety and Medical Affairs functions can expect below outcomes:

- Collaborative content management platform for sponsors, clinical sites, IRBs and investigators to work together
- Automated protocol document generation, clinical study report, eCTD, safety, narratives and product labeling
- Enhanced review, quality checks and audit trail across entire clinical development cycle
- Consistent and real-time medical information for HCPs and patients