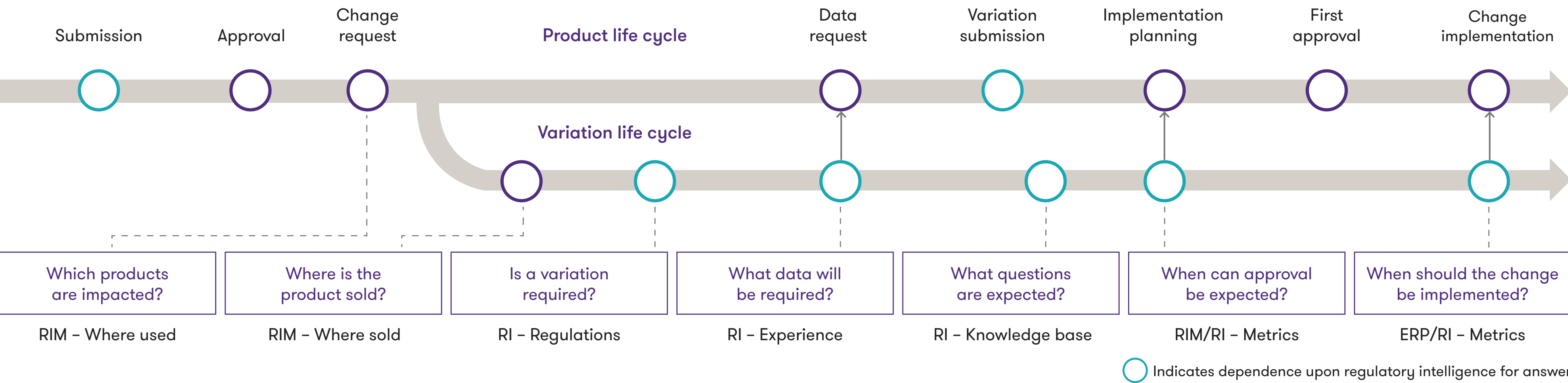


Fixing change control and variation management

RI informs regulatory, labeling, manufacturing and supply chain activities throughout the product life cycle



Managing change to products and manufacturing processes is one of the most complicated cross-functional capabilities. Regulatory intelligence plays a critical role supporting:

- Variation filing determination for each country, as well as how many variation filings are permissible in a given year
- Change bundling and planning decisions

- Variation submission content decisions across all markets
- Implementation planning based upon expected approval times (leveraging upon previous approval experience)
- Implementation timing based upon expected approval times and remaining pre-change stock
- Post-change implementation notification requirements