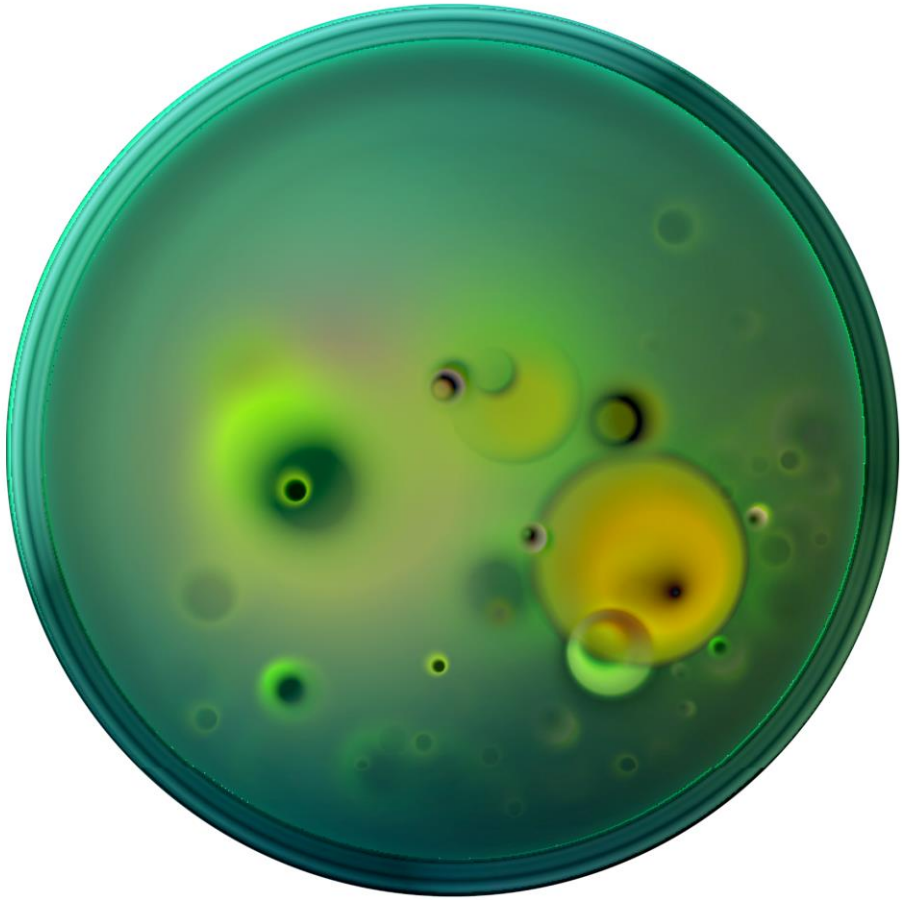
Deloitte. KING & SPALDING NKF

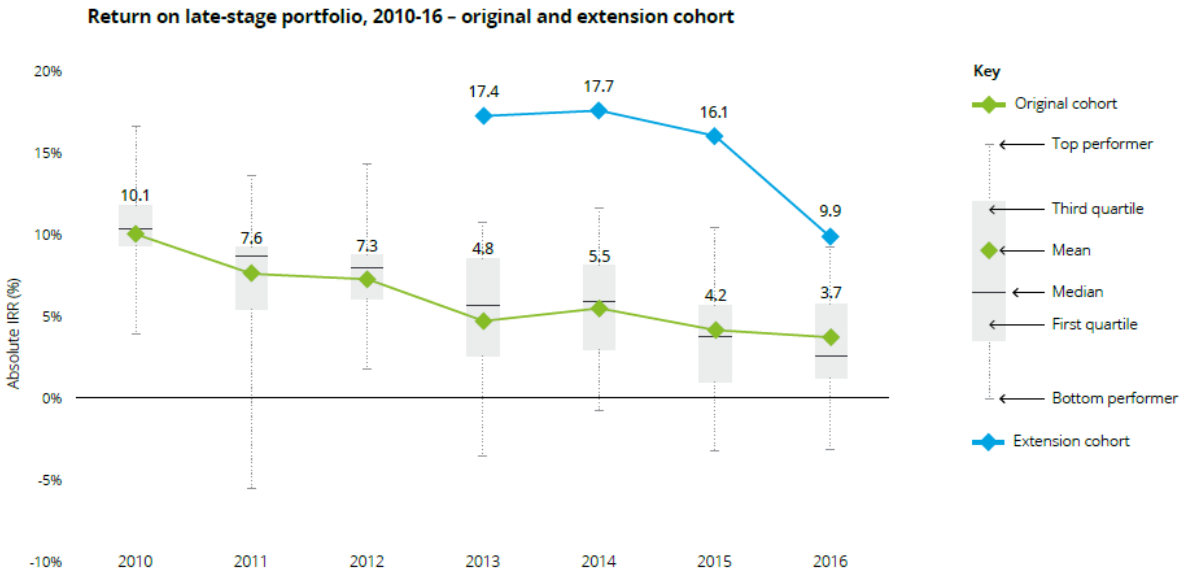


Innovation risks roundtable

21 March 2017

Return on pharmaceutical innovation at an all time low

Digital innovation is a mechanism that has been suggested as a means to improve returns on innovation, but the risk must be managed



Source: Measuring the return from pharmaceutical innovation 2016, Deloitte

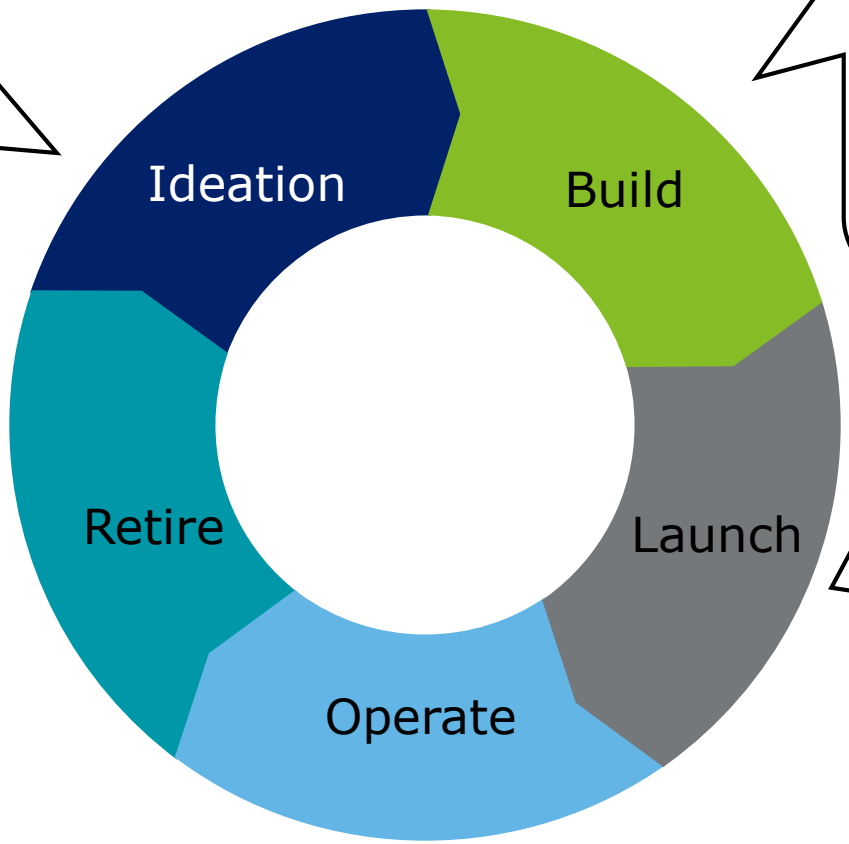
Digital innovation concepts: a potential solution to declining ROI

- **Cutting direct development costs:** Digitisation of systems supporting the development process to optimise meta activity associated with medicines development and produce greater insight through analytics.
- **Reducing trial duration:** Gather evidence to support clinical study endpoints via devices, digital patient recruitment and investigator engagement platforms to accelerate trial completion and potentially earlier licensing as well as reducing overall trial costs due to shorter duration.
- **Increasing peak sales:** Understanding outcomes for patients through real world data collection via digital means e.g. patient communities, platforms and patient connected devices; Using digital technologies to put decision support systems in the hands of physicians for better diagnosis for rare or special conditions; utilising data collected to support pricing and reimbursement discussions.

An innovation lifecycle approach to risk

Managing risk from digital innovation has a class of actions at each stage in an innovation lifecycle

Risk scoping, i.e determining the potential regulatory and other risk categories applicable to the asset. Risk scoping then drives a risk **assessment** to classify the risk and trigger **risk planning** activities.



Build mitigating controls that are identified or prescribed as a result of the risk planning activity. **Maintain evidence of quality** during the build process for potential registration or as evidence should an issue arise. **Confirm risk assessment** is appropriate based on the actual build outcome.

Implement the **Information recovery** and safe disposal plan for the asset including **Archiving** of data. **Assess learnings** and update risk models.

Activate monitoring capability to support the requirements in the risk management plan. Mobilise the **Intensive care support** for launch to respond to unexpected issues. Test the **Crisis management response plan** if required by the risk mitigation plan.

Integrate the innovation into the business as usual **Risk assessment and Compliance assessment** processes including **PV** aspects as well as manage other risk (e.g. off label claims)

Case Study

Life Sciences company using devices to capture clinical study data

context

- The company wanted to collect additional data about how the study drug was used by patients in addition to self recorded (ePRO) data.
- A computer chip was inserted in the delivery mechanism to monitor use (dosage, frequency, ToD) by the patient. The data was then uploaded via Bluetooth connection to a mobile phone and then from the phone to a data processor via the internet.
- The data was compiled by the processor and supplied to the pharma co with the intention that it be submitted as part of the evidence supporting the study conclusions.

ideation	build	launch	operate	retire
A risk assessment was not conducted at inception. As a result not all the potential areas that should have been considered were incorporated in the planning and design of the system or in the management of the 3rd parties and vendors.	System development standards were not applied consistently across the development process and continued into maintenance of the production environment resulting in significant device failures. Risks and compensating controls were not assess and designed. Cyber vulnerability assessment was not conducted.	Capacity planning was not undertaken, causing data loss and resulting in remediation requirements in mid study as data volumes started to exceed system capability. No operational management plan, including an incident management plan, was put in place resulting in an ad-hoc remediation effort.	A control framework was not in place to monitor for errors, procedures could not be evidenced and end to end integrity of data could not be demonstrated. Management of the validation status of the system was not maintained although the organisations individually claimed the validation status of their own components of the system	Ownership of "know how" was not clearly defined at the outset of the trial. Additional provision had to be made to retrieve and "wipe" devices used in the trial.

Impact

- Study data corrupted with consequent questions over usefulness of the data
- Inability to demonstrate the validation status of the system
- Potential for unidentified risk exposure

Niederer Kraft & Frey

Data privacy and antitrust aspects

Managing personal data from digital innovation at each stage in an innovation lifecycle

Ideation	Build	Launch	Operate	Retire
Type of data collected Notifications to data subjects Consents Notifications/registrations with Data Protection Authorities Indication of purpose Registration of data collections Overriding regulatory provisions	Design data protection structure Location of servers Grant access rights Privacy impact assessments – privacy by default – privacy by design Cross-border transfer / data flow: e.g. BCR, EU model clauses, Privacy Shield Appointment of DPO	IT policies Websites with cookie and privacy policies Terms & conditions with privacy terms Compliance with all requirements under the Data Protection Act and applicable regulatory provisions Outsourcing of data processing	Comply with data processing rules Implementation and use of monitoring / compliance software Whistleblowing Hotlines Information and access rights of data subjects Keeping personal data up to date and correct Disclosure of personal data in administrative and court proceedings – blocking statutes Ensuring data security	Archiving Personal Data Deleting Personal Data Systems for data destruction Right to be forgotten

Antitrust issues at each stage in an innovation lifecycle

Ideation	Build	Launch	Operate	Retire
If ideation process is purely within group, no risk of actual infringement at this stage However, already at early stage of ideation process, all the areas of concern should be considered and incorporated in the planning and design of the project Therefore, typically, the entire lifecycle should be reviewed also from an antitrust point of view This will enable to foresee already at this stage what will be the limits, opportunities and options To know about this is often critical for the design of a project The pharmaceutical industry is in the focus of the antitrust authorities (and other authorities)	Where possible, conclude agreements in accordance with Block Exemption Regulations (BER) to benefit from exemption: ▪ Technology Transfer (license) Agreement BER ▪ R&D Agreement BER ▪ Specialisation Agreement BER ▪ Vertical Agreements BER Techn. Transfer BER: ▪ Market share below 20/30% ▪ No hard-core restrictions If BER do not apply, case by case analysis In CH BER not applicable Note: If (full-function) joint venture is made with other undertaking (competitor or not), this will normally qualify as a merger and, if turnover thresholds are met, be subject to merger control	Horizontal -> Avoid hard-core restrictions (depending on type of agreement, partly with exceptions): ▪ price fixing, ▪ limits on quantities of goods/ services to be produced, purchased or supplied, ▪ allocating markets or customers, ▪ restricting licensee to exploit its own technology ▪ sharing of sensitive information (also hub and spoke through third party, e.g., distributor, trade association) Vertical -> Avoid hard-core restrictions: ▪ restriction of parallel imports (e.g., by restricting passive sales; in CH partly wide interpretation of Cartel Act by COMCO), ▪ resale price maintenance (RPM).	Co-promotion (co-branding) agreements (joint selling/ marketing of single product under single brand) may raise concerns if they result in price fixing, limiting out-put, market sharing, revenue sharing, exchange of sensitive information among competitors Co-marketing agreements (joint selling/ marketing of single product under different brands) are less likely to raise concerns if parties bear own responsibility for setting prices/ strategy and do not share revenues and exchange sensitive information Lifecycle management strategies (filing series of patents for same product / second generation products) alone are unlikely to infringe antitrust, unless, e.g., dominance cases (see column right)	Industry-wide monito-ring and enforcement focus re patent settlements: antitrust concerns, where effect of delaying or limiting entry of generic drugs onto a market. Critical: value transfer (pay-for-delay) Dominant Position: If company has dominant market position, special responsibility not to engage in certain exclusionary or exploitative conduct Dominance cases include: Submission of misleading information to obtain patent (exclusive right), litigation only to harass other party or to eliminate competition Note: Not only risk of fines, but also risk of damages actions in EU. In CH hardly any damages actions based on antitrust infringements yet. Political debate

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King and Spalding

Life Sciences: U.S. Enforcement and Cross-Border Investigations

Intersection of U.S. law enforcement and European-based life sciences companies in clinical studies

Consider the broad jurisdiction of a law like the U.S. foreign corrupt practices act (FCPA)

The FCPA covers actions outside the U.S. by:

- Non-U.S. subsidiaries or joint ventures of issuers of U.S. parent companies
- Non-U.S. agents acting on behalf of issuers or U.S. companies
- Non-U.S. persons acting while in the territory of the U.S., for example:

"Placing a telephone call or sending an e-mail, text message, or fax from, to or through to United States involves interstate commerce – as does sending a wire transfer from or to the U.S. bank or otherwise using the U.S. banking system, or travelling across state borders or internationally to or from the United States"
See U.S. Department of Justice & U.S. Securities and Exchange commission, A resource guide to the U.S. foreign corrupt practices Act at 11 (Nov 14, 2012)

And, the U.S. enforcement authorities are implementing these theories successfully

- Seven out of the top ten resolutions involved companies with headquarters outside the U.S.
- Life Sciences companies have paid nearly $1 billion in FCPA fines and penalties in the last 10 years

Cross-border investigations

Issue identification – preparing for a Government inquiry

- Have independent, outside counsel identified ahead of time (U.S. and local counsel)
- Move quickly to launch internal investigations
  - Preserving and reviewing information
  - Conducting employee interviews
  - Reporting findings internally
  - Assessing additional steps

Reporting and cooperating with U.S. Government investigations

- Elements of cooperation: document production, interviews, presentations
- Sequencing and coordinating across jurisdictions (e.g., Swiss authorities and U.S. authorities)
- Remediation efforts

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Discussion

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