The Impact of Brexit for a Clinical Trial Project Manager…

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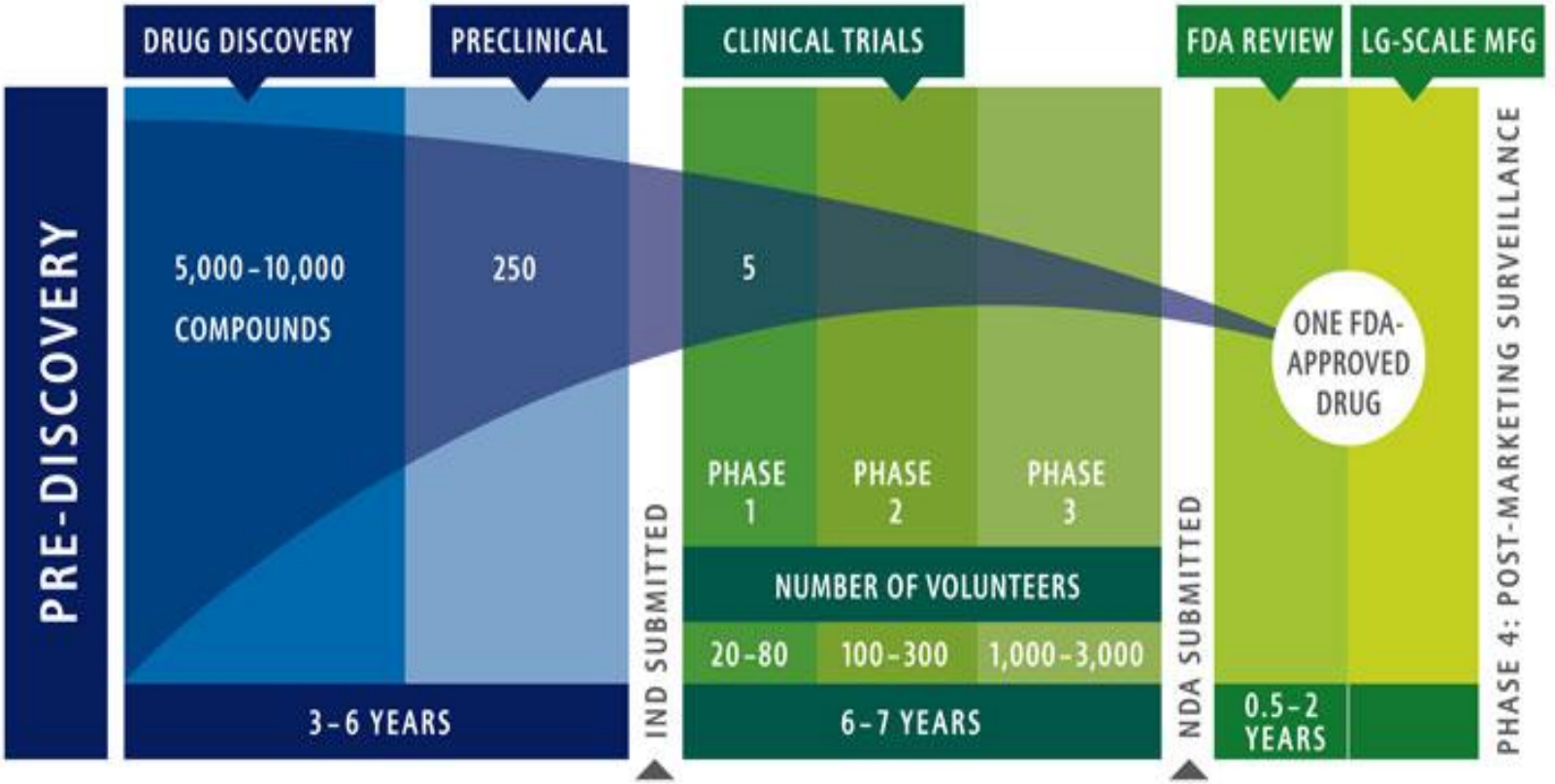
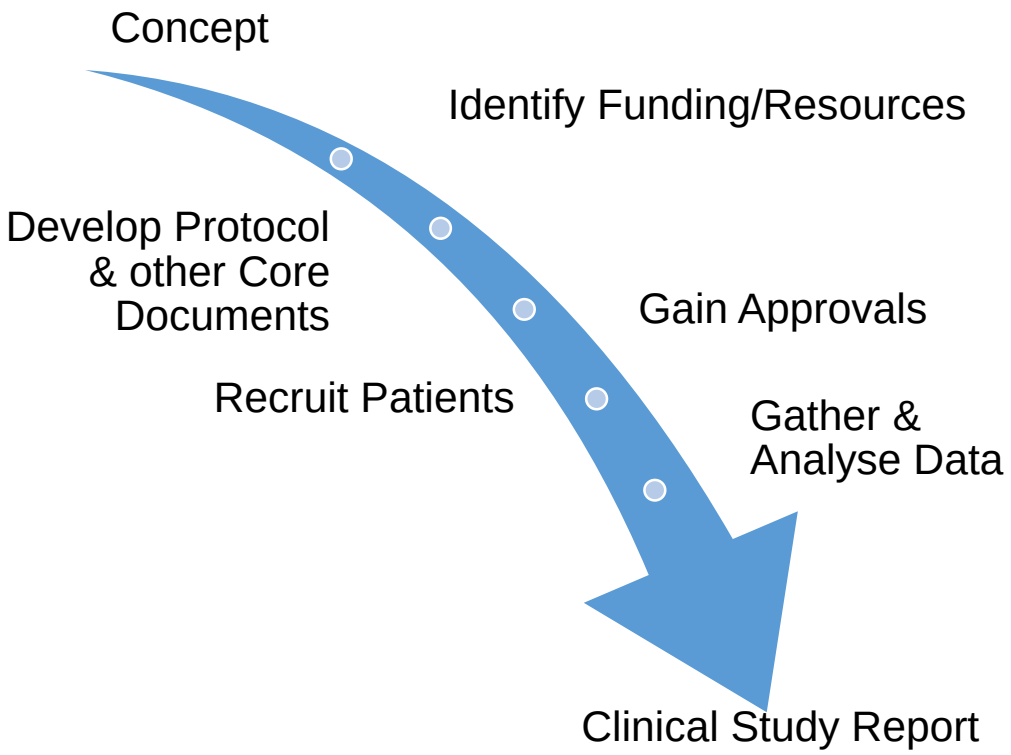
Drug Discovery and Development: A LONG, RISKY ROAD



Source: Pharmaceutical Research and Manufacturers of America

A typical clinical trial



Hard Brexit: hard knocks

- UK excluded from EU/EEA infrastructure
  - Regulatory
  - Commercial
  - R&D funding, collaboration
- Loss of EU nationals
- Loss of EU bodies
- No freedom of movement
- Trade restrictions, tariffs
- ICH status?

Hard Brexit: Europe's loss

- MHRA - world class regulator
  - Highest EU workload contributor
  - Most used Rapporteur and RMS
  - Top table MS regulator
  - NIBSC science base
- NICE - respected and influential HTA body
  - UK reference pricing benchmark
  - TAs are EU are gold standards
- Relocation of EMA
  - Loss of staff
  - Stalling of progress

Hard Brexit: Mitigations & Opportunities

- Mutual recognition agreements
  - Modelled on Switzerland, Canada & Australia
  - Rubber stamping by MHRA- unlikely!
- National removal of bottlenecks
  - Clinical Trials Directive 2001/20/EC*
  - Drug/device combination products
  - Regulation of companion diagnostics
- Regulation of advanced therapies
- Use of real world evidence (for MAA/HTA)
- Evolution of EAMS (PIM, opinion stages)
  - Dovetailing with HTA

* Europe's gift to America (FDA)

PM Risks

- Permissions – access to EU Portal?
- Logistics - shipping drugs/samples/supplies?

Reality Check as a PM

- Location UK only/European/Global?
- Timing – 2019? Keep calm and carry on?