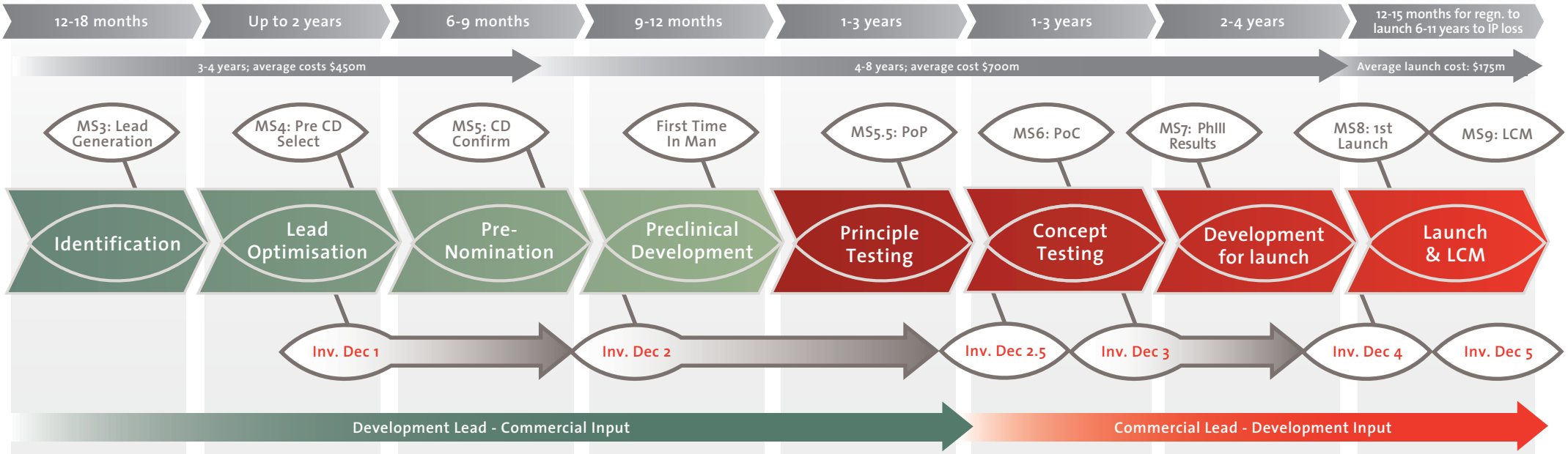
Investment Decision Process

Atebion BDS can support at each and every development stage and ID point

Typical Timelines and Costs By Stage



Core Commercial Considerations

- Disease TPP and CDTP
- Unmet needs
- Market overview
- Broad commercial potential
- IP viability

- Project TPP
- Define key attributes
  - Optimal formulation
  - Dosage requirement
  - Profile pre-requisites
- Define IP Strategy
- Define Regulatory Strategy

- Market Overview
- Clincal vs commercial needs by Region & Key Market
- Competitive landscape
- Emerging Markets strategy

- Refine TPP
- Define TPC
- Key Market forecast
- P&MA
- Value proposition

- TPC aligned with candidate
- P&MA strategy
  - Value demonstration plan, value-added TPCs
- Detailed forecast & Market insight
- Strategy for 'Development for Launch'
- Review / Update IP strategy IP health check
- TM & Publications Plan

- Brand strategy plans for launch
- Refine detailed forecasts by market
- Development of LCM plans
- Agree commercial product design
- Patient segmentation & profiling
- Value Story

Core Technical / Clinical considerations

- DMPK in vitro, in vivo
- Hit to lead chem for structure/ activity relationship
- Safety Assessment
- Efficacy & safety screening plan
- Quantitative potency defined
- Selectivity targets for CDTP

- Explore PR&D scale-up & suitability for pharmaceutical development
- Preliminary safety / tox pharmacology
- G/no go for hypothesis testing based on CDTP
- Plan for up to PhI

- Additional safety evaluation
- PR&D, PAR&D evaluations
- PoP study outline defined
- Synthetic route evaluation
- Formulation studies

- GLP pivotal tox studies
- Safety pharmacology
- Approval for 1st IND/CTA
- Initiate SERM meeting
- Bulk drug / formulation to support PhI/II
- HELC approval for SAD studies
- Reg approval for FTIM

- Safety data for concept data available
- Safety, tolerability, pK for several doses
- Determine dose range for PhII studies
- Submit IND/CTA
- Technical feasibility confirmed
- Define strategy for PhI and PhII

- Further safety, tolerability, pK, PD
- Efficacy and safety in target population
- Probability risk assessment
- Regulatory risk assessment - dialogue with Authorities
- Market formulation defined
- Supply chain and sourcing plan agreed
- PhIII & LCM programme designed, go / no go agreed
- Reg Authority consultation / approval for PhIII

- Demonstrable proof of safety & efficacy in lilne with TPP & TPC
- Benefit: risk confirmed
- Finalise supply chain
- Prepare regional prescribing information
- Clinical phase IIIb / IV plans in line with TPP
- Submission strategy with HAs
- Submit NDA / MAA dossier
- Update regulatory risk
- Obtain Product License