

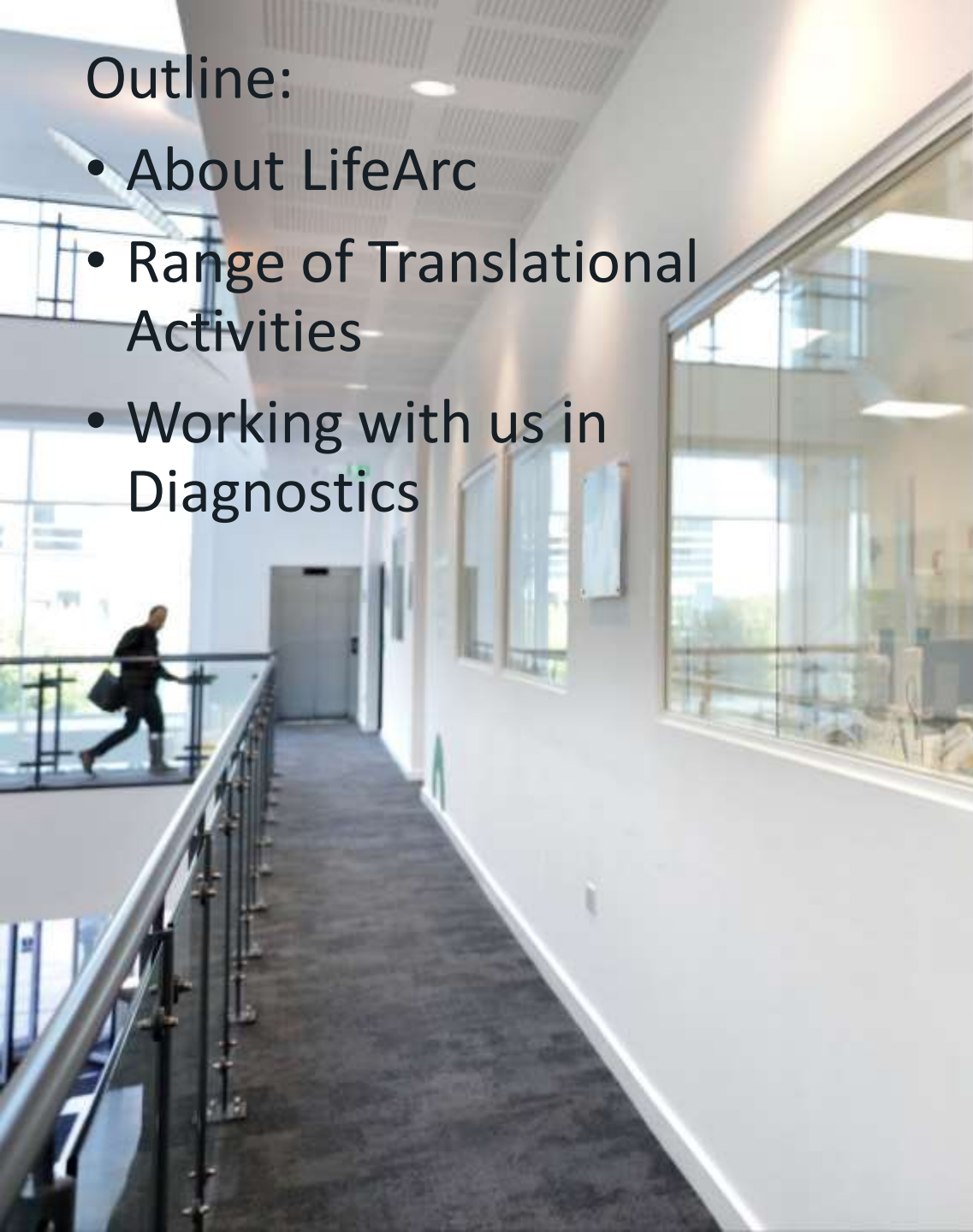
Helping turn great science into greater patient impact

April 2019

Dr Mike Dalrymple, Director Diagnostics

Outline:

- About LifeArc
- Range of Translational Activities
- Working with us in Diagnostics



LifeArc

The bridge between
research and improving
patients' lives.

Who are LifeArc?

- A cross-border charity in the UK
- 'Translating' academic research
- Life Science specialist
- Founded in mid 1980s
- 30+ years in the 'technology transfer' business
- Key Client: UK Medical Research Council
- Collaborating widely - UK, Europe, USA, China



LifeArc

Our Organisation Today

Our ambitions driven by our Charitable 'Objects'

'To promote the public benefit by improving human health and medical research...

'Accelerate the progress of these discoveries and technologies to the stage at which they are (i) capable of being made generally available to the medical profession and the public for practical application for the improvement of health and/or (ii) are transferred or licensed to a third party to progress development of such discoveries or technologies towards such goals'

- Over 180+ Staff, on three sites including...
 - 30 in *Technology Transfer* (London)
 - 90 *Drug Discovery* scientists (Stevenage)
 - 15 *Diagnostics* scientists (Edinburgh)
- We are financially self sufficient -
 - Revenue (2017/18) £25.85m
 - Expenditure (2017/18) £26.54m
- With our R&D spending, we have invested over (2017/18)-
 - Drug Discovery £16.2m
 - Diagnostics Development £2.2m
- We have also invested over £19m in a new Drug Discovery Complex (Stevenage) & Diagnostics Development Centre (Edinburgh)



LifeArc translational success in numbers



NUMBER CRUNCHING

3 small molecule programmes successfully partnered with industry

4 'own risk' antibody programmes partnered

1 Dx project partnered



NUMBER CRUNCHING

60 antibodies humanised over the last 30 years

19 antibodies entered in clinical trials

5 antibodies currently in clinical trials



NUMBER CRUNCHING

4 humanised antibodies currently on the market

1 Dx product on the market

We are self-funded from royalties

LifeArc

biogen idec

Roche

Takeda

MERCK



MS



RA



CD / UC

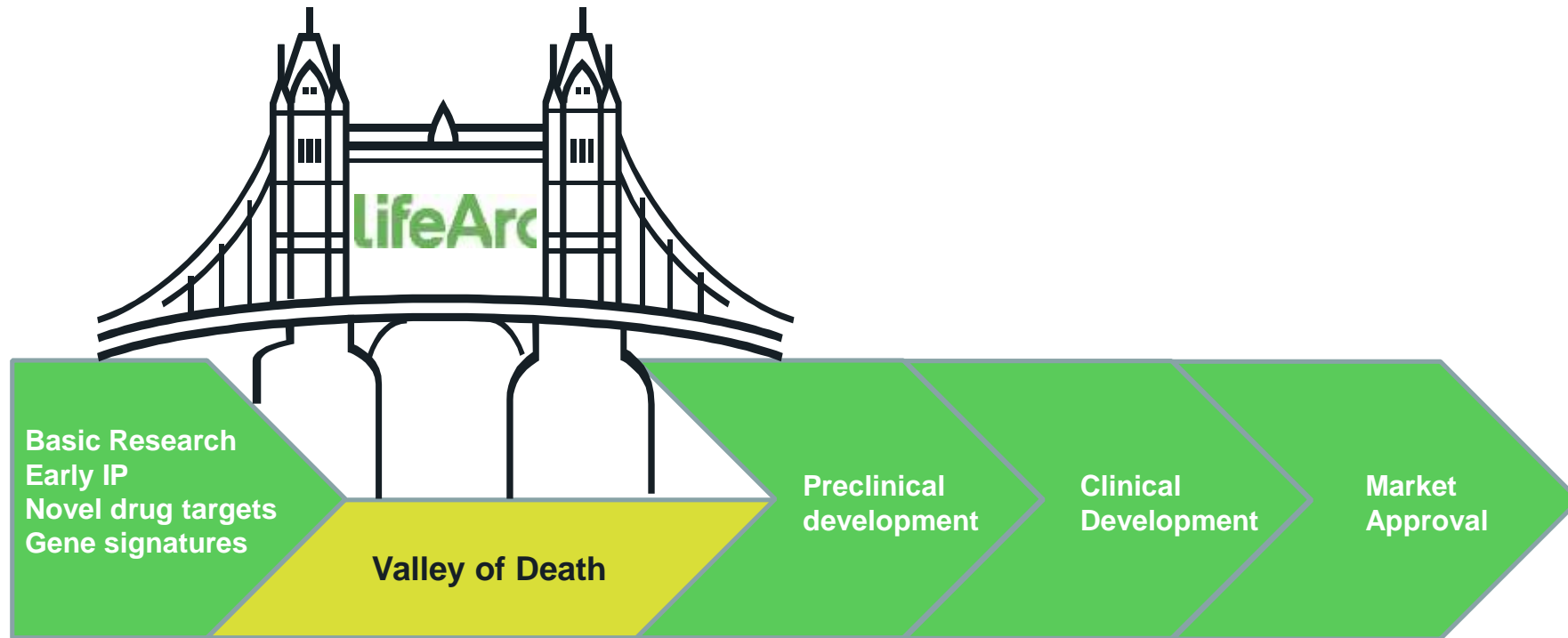


Cancer

LifeArc

A Range of Activities

Bridging the translation gap



A toolkit of expertise, resources and finance

LifeArc

Technology
Transfer

LifeArc

Centre for
Therapeutics
Discovery

LifeArc

Centre for
Diagnostics
Development

LifeArc

Funds

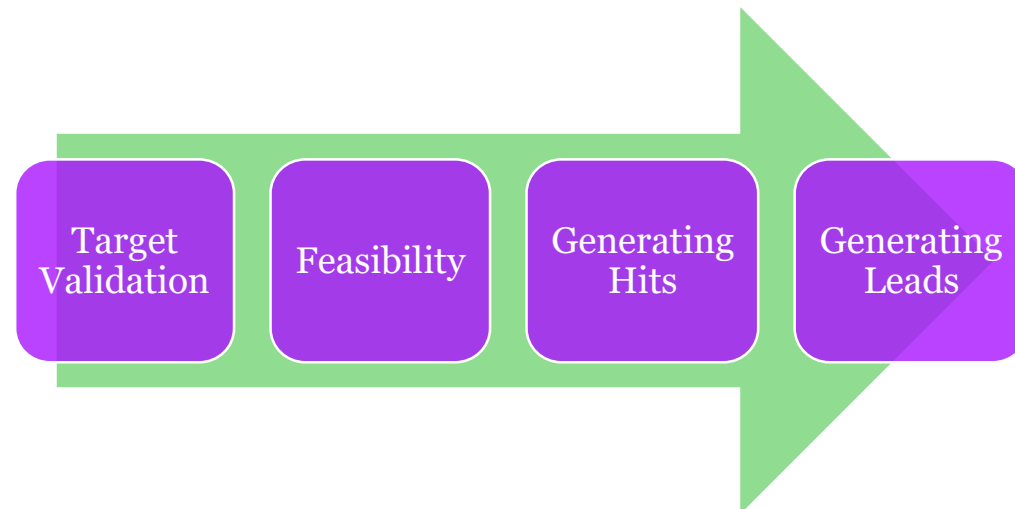
Technology Transfer

- A large, experienced group of IP and TT professionals
- Strategic relationships with the MRC, LSHTM and others
- Service offering to medical charities (over 70 since 2012)
 - Portfolio Review Service
 - Advisory Services

No cost model – either *pro bono* or shared risk

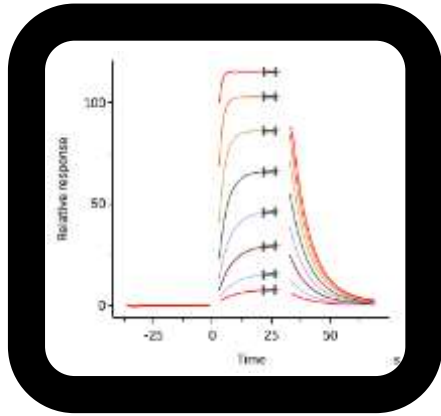
The Centre for Therapeutics Discovery

- Bridging the gap between basic research and early drug discovery
- Working with industry, charities and universities
- A purpose built LifeArc facility opened April 2016
- > 90 scientists
- State-of-the-art equipment and capabilities
- Biology, Chemistry and Biotherapeutics teams in one place offers unique flexibility

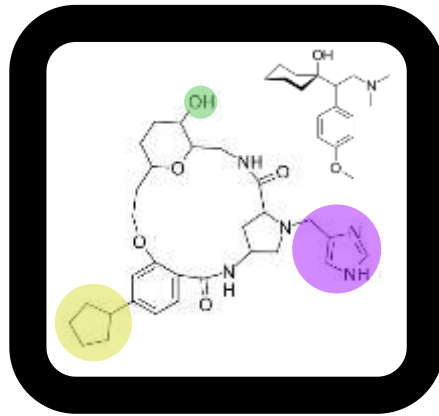


The Centre for Therapeutics Discovery

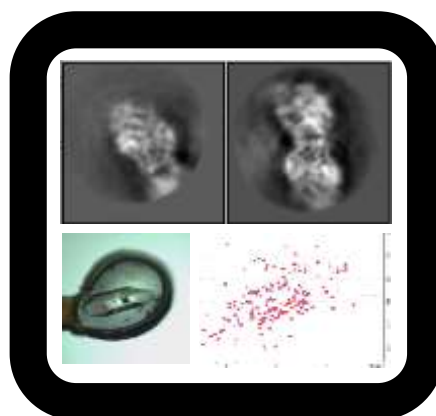
Biophysics



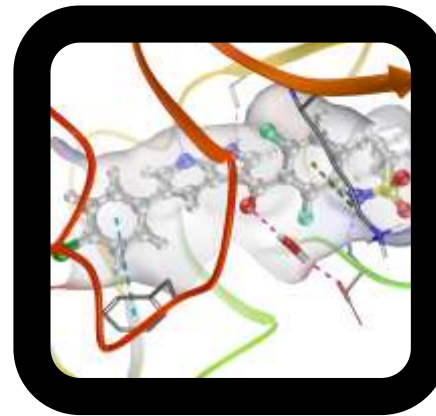
Compound Libraries



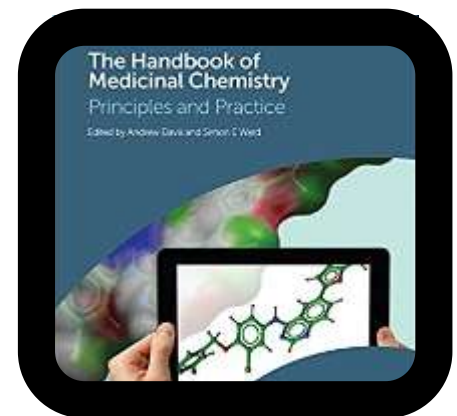
Structural Biology



Rational Drug Design



Medicinal Chemistry



Target Confidence

Assay Development

Hit Generation

Lead Identification

Lead Optimisation

Biotherapeutics



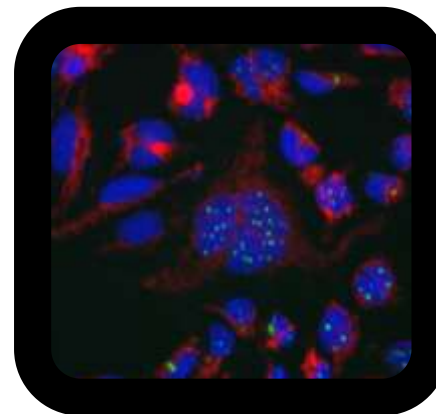
Assay Development



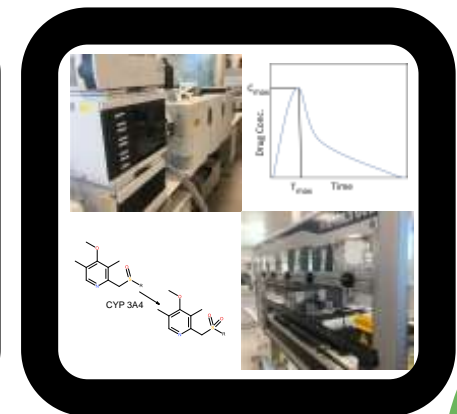
HTS Screening



Pharmacology



ADME profiling



LifeArc

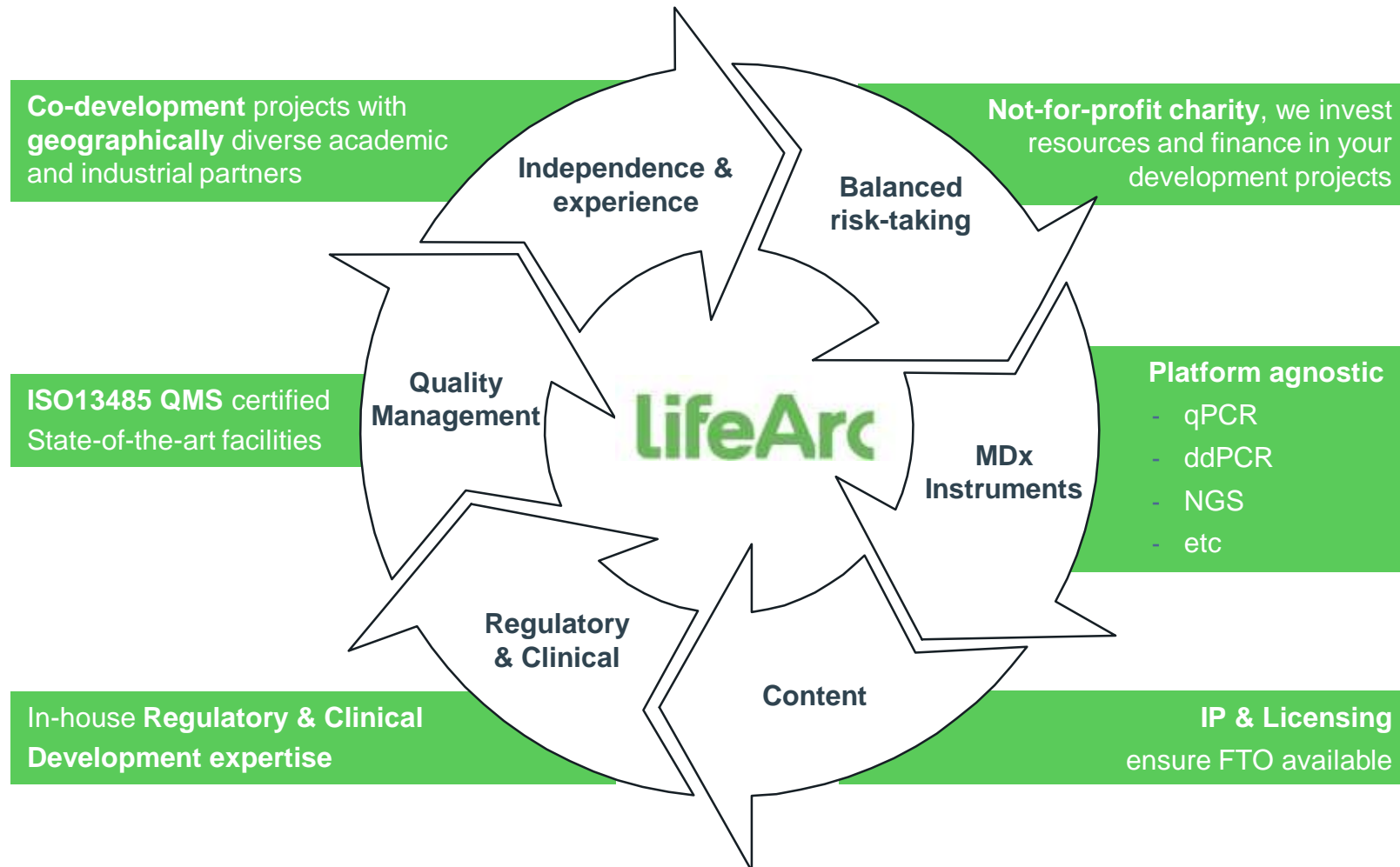
Working with us in diagnostics

The Centre for Diagnostics Development

- Experienced team of assay & clinical development scientists
- Work under industry standard Project Management & Quality Management practices (ISO13485 accredited)
- Located beside Edinburgh's main acute hospital (ERI), Edinburgh University and biotech hub



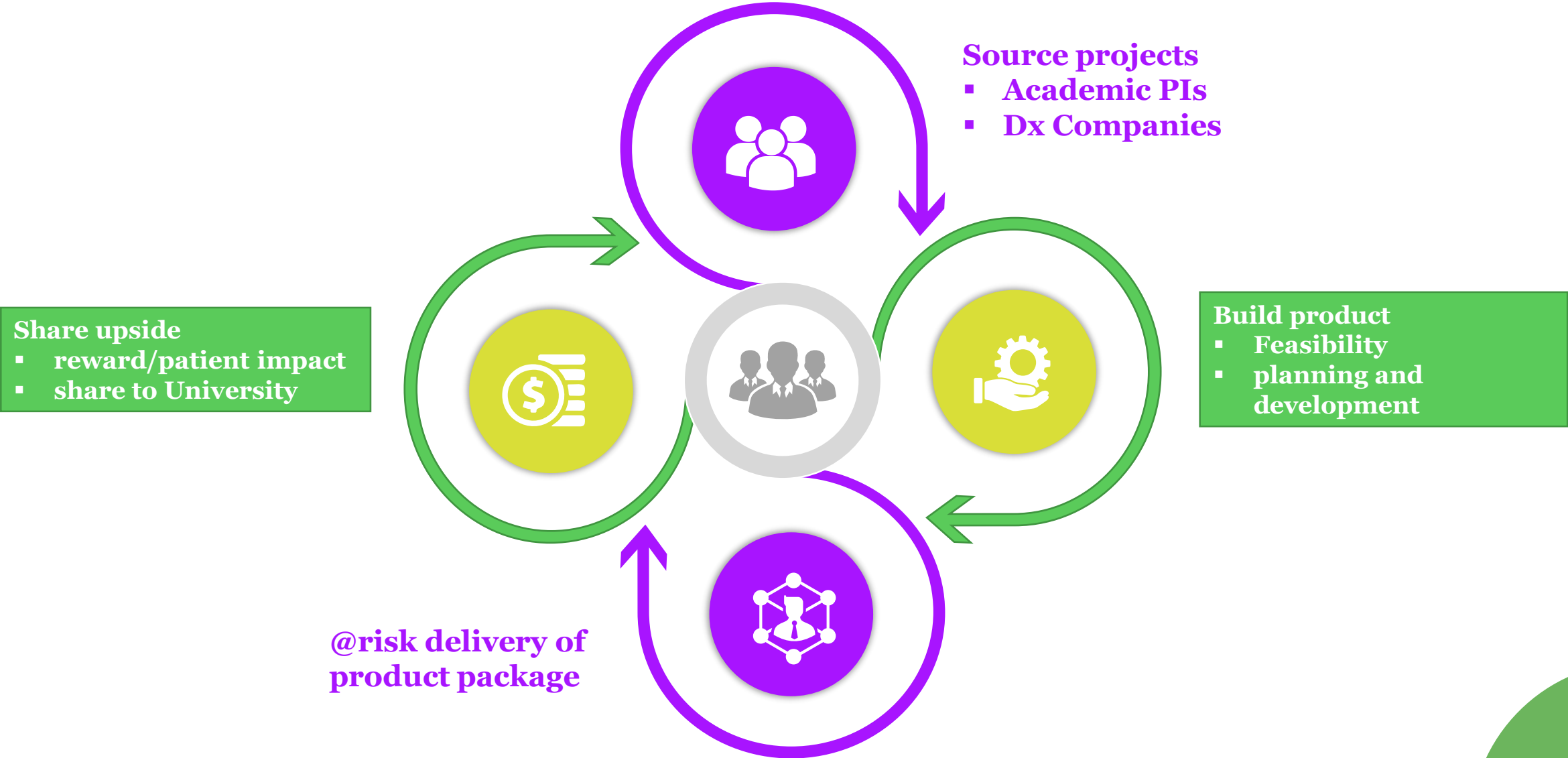
CDD & Diagnostics Partners



- Patient benefit the key driver
- Best platform for clinical need
- Industry standard processes
- Compilation of technical file

Assay development according to Design Control to ensure smooth transition to full IVD product development

Our business model



Building a Dx project at LifeArc

Mutations/Signatures associated with disease or disease progression:

- Statistically significant data
- Bench assay
- Access to stored samples
- Clinical collaborators

Discovery (Potential Dx)

Feasibility

Design & Development

Project Review (Stage 1):

- Scientific Landscape
- Clinical relevance
- Consider unmet need, IP, commercial landscape
- Reproduce and extend key data
- Assess best delivery platform

Project Review (Stage 2):

- Project plan and resourcing
- Platform selection
- TPP, Intended Use, pathway analysis, reimbursement, barriers to adoption, KOL interviews
- ISO13485
- RUO kit or CE-IVD

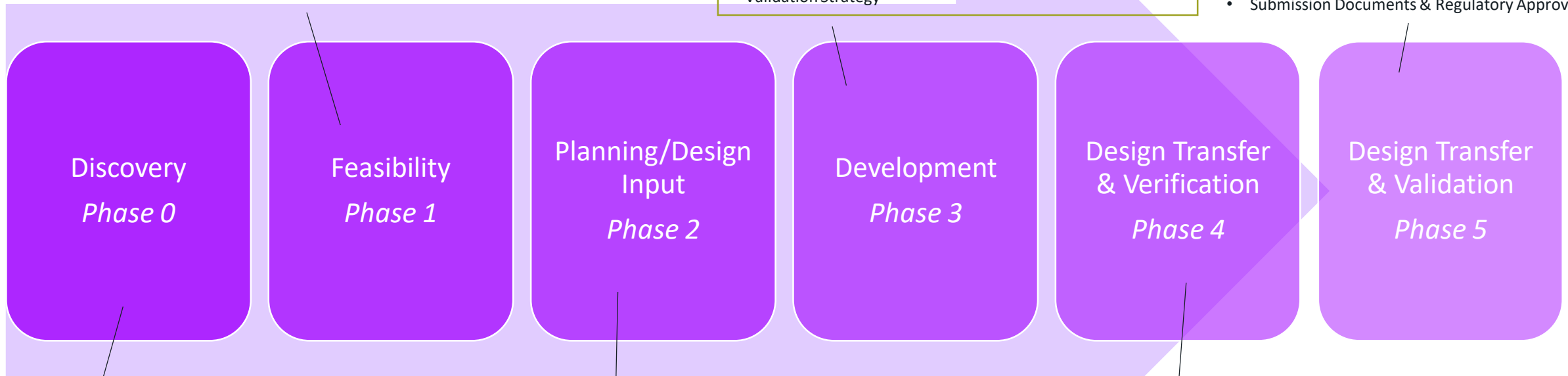
What will we do? Design & Development - Design Control

- Completed Project Charter
- Feasibility Report
- Intended Use Statement
- Product Requirement Specification (Market/User Needs)
- Initial Patent Report
- Confidential Disclosure Agreement (CDA)/Material Transfer Agreement
- Project agreement
- IP protection agreement

- Development Report
- Draft Quality Control and Manufacturing Documents
- Risk Analysis and Risk Management Report
- Regulatory Strategy reviewed
- Budget
- Verification Strategy
- Validation Strategy

- Updated OAG Assessment
- Bill of Materials (BOM)
- Stability Study Protocol
- Transport Study Protocol
- QC Panel
- Draft labels and packaging

- Process Validation Protocol (complete)
- Process Validation Report
- Product Validation / Clinical Report
- Regulatory Strategy reviewed
- Budget
- Review Risk management plan
- Risk Assessment and Risk Report
- Manufacture Report of Validation Batches
- Updated OAG Assessment
- Submission Documents & Regulatory Approvals



- Confidential Disclosure Agreement (CDA)/Material Transfer Agreement
- Project Agreement
- Outline Project Charter
- Discovery Report
- Draft Intended Use
- Market Potential Summary
- Nominated and internally agreed partners

- Product Requirement Specification/User Needs/ Clinical Background
- Design Inputs
- Design Development Plan
- Regulatory Strategy
- Budget
- Risk Management Plan
- Initial Risk Assessment
- Establish Design History File (DHF)
- OAG Assessment/IP Report

- Verification Protocol (complete).
- Verification Report
- Regulatory Strategy reviewed
- Review Design and Development Plan
- Product Validation/Clinical Strategy
- Training Materials
- Budget

- Review Risk management plan
- Risk Assessment and Risk Report
- Manufacture report of Verification Batches
- Prototype labels and packaging
- Audit Plan for Critical Suppliers
- Updated OAG Assessment
- Product Launch Plan

Commercial Collaboration

A diagnostic test for antibiotic resistance

- Objective
 - Develop content for the RenDx assay pipeline
 - Proprietary technology – SERRS enabling multiplex detection
- What we did
 - Developed ‘Carbaplex’ – multiplex assay for all major carbapenemase markers in CPE
 - Resistance to carbapenems, the antibiotics of last resort, a pressing medical crisis – facilitating rapid detection in hospital setting.
 - Technology acquired by Bruker Daltonics, now marketed as Carbaplex[®], qPCR assay.



Commercial Collaboration – Biocartis co-development of a Breast Cancer assay

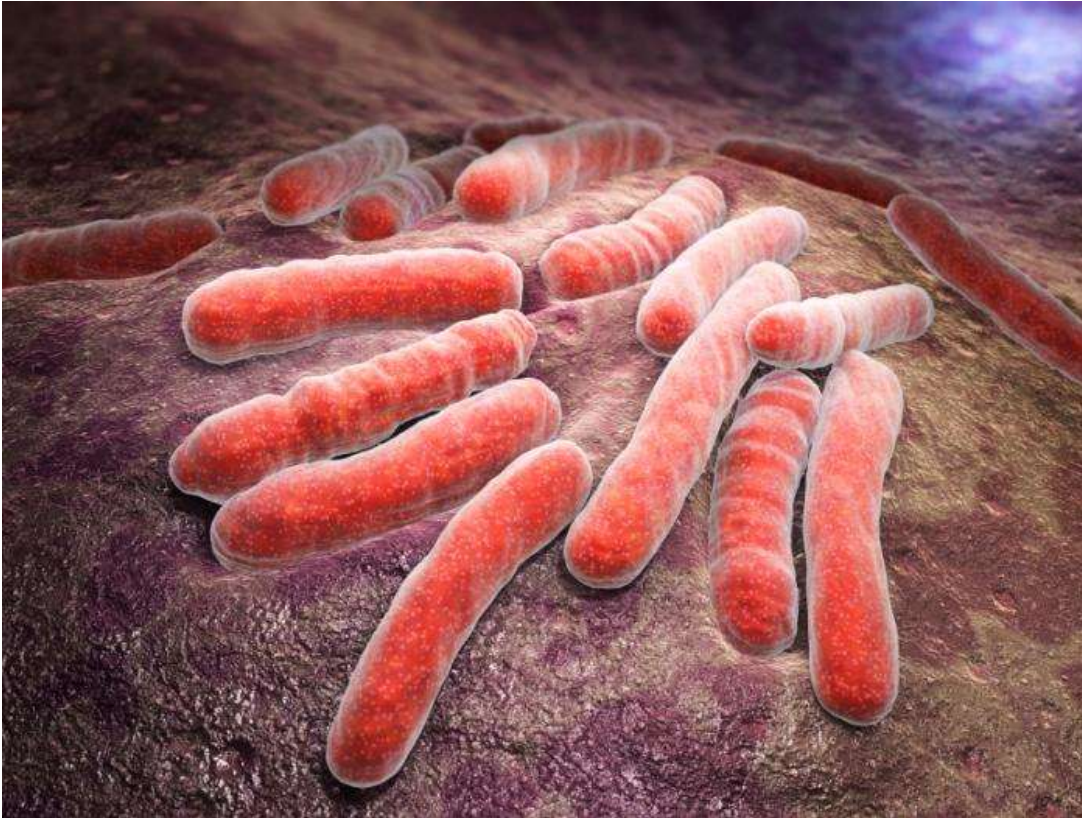


- Molecular diagnostics company based in Belgium
- Proprietary Idylla platform: fully automated, real time qPCR system; accurate, highly-reliable molecular information from any clinical sample
- Idylla system covers entire process from sample to result in about 35 to 150 minutes with less than 2 minutes hands-on time
- Biocartis developed assays in oncology (KRAS, NRAS, EGFR & BRAF, RUO & CE-IVD) and infectious diseases (IFV-RSV, FDA cleared); the platform is FDA waived & CE-IVD marked
- LifeArc currently developing an advanced breast cancer assay



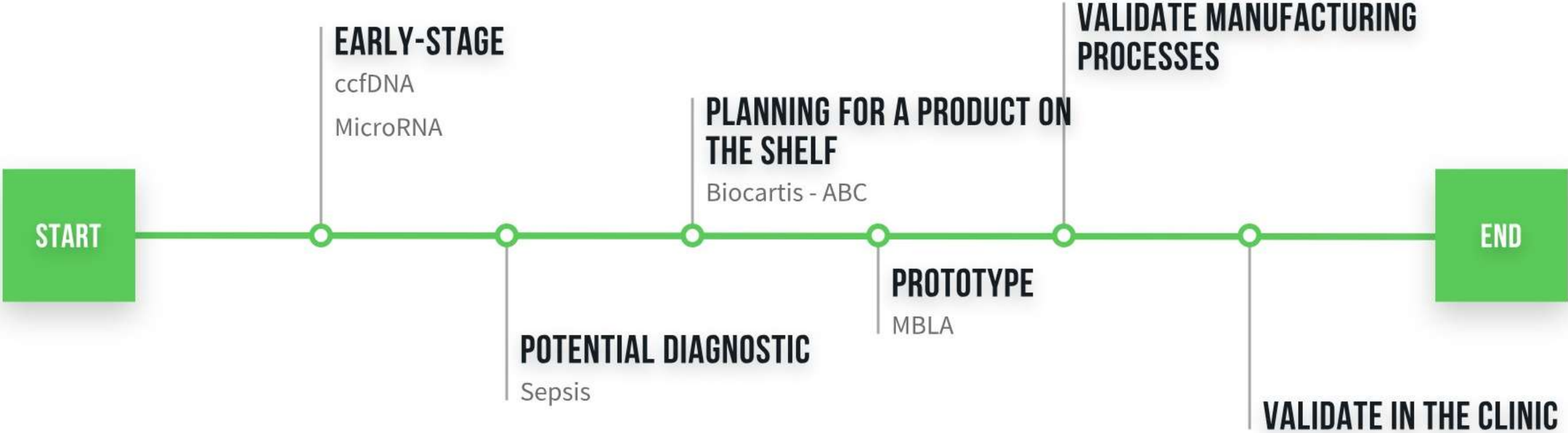
Academic Collaboration: St Andrews

Molecular Bacterial Load Assay: Fast & Accurate Monitoring TB Treatment Response



- Target: 16S rRNA of MTB
- Collaborator: Professor Stephen Gillespie
- Intended Use: diagnosis, treatment monitoring & confirmation of cure
- TPP: defines use with limited resources

Current Pipeline





Contact LifeArc

michael.dalrymple@lifearc.org

Visit our website: [LifeArc.org](https://lifearc.org)

