



Company and Capabilities Overview

Summary Overview

Team

- dedicated employee-based global team of drug development experts that advise and manage Client programs and projects
 - Focus - early stage projects from chemistry, nonclinical & regulatory filing through Phase 2 Proof of Concept

Clients

- spread across the globe in US, EU, Asia and Australia
- emerging companies, pharma, entrepreneurs, investors...

Operations

- utilize well defined processes with integrated teams leveraging document sharing systems (SharePoint) and appropriate level interaction with all parties (client, vendors, investors...)

Expertise

- team members have 15+ years of drug development and regulatory experience from large Pharma and Biotech

Drug Development Experience

Experienced in the preparation and filing of IND's, CTA's, NDA's and MA's

- Currently managing and filing ~3-5 IND/CTA each year
 - “no projects on hold with the authorities”

Development areas:

- CMC, PK/PD, NonClinical, QT, Regulatory, Phase I, Phase II POC, eCTD's...

Therapeutic areas:

- CNS, CV, Oncology, Respiratory, Rheumatology, Dermal, Immunomodulation, etc...

Program types:

- Small molecules, oligos, proteins, peptides, cell based therapies, etc...

Service Offering Overview

Fully Integrated Preclinical and Clinical Development Programs

- Stand-alone virtual team model
- Integrated partnering model

Gap Filling and/or One-Off Projects

- Independent discreet projects
- Staff supplement

Due Diligence / Program Assessments

- Stand-alone programs or full portfolio assessments

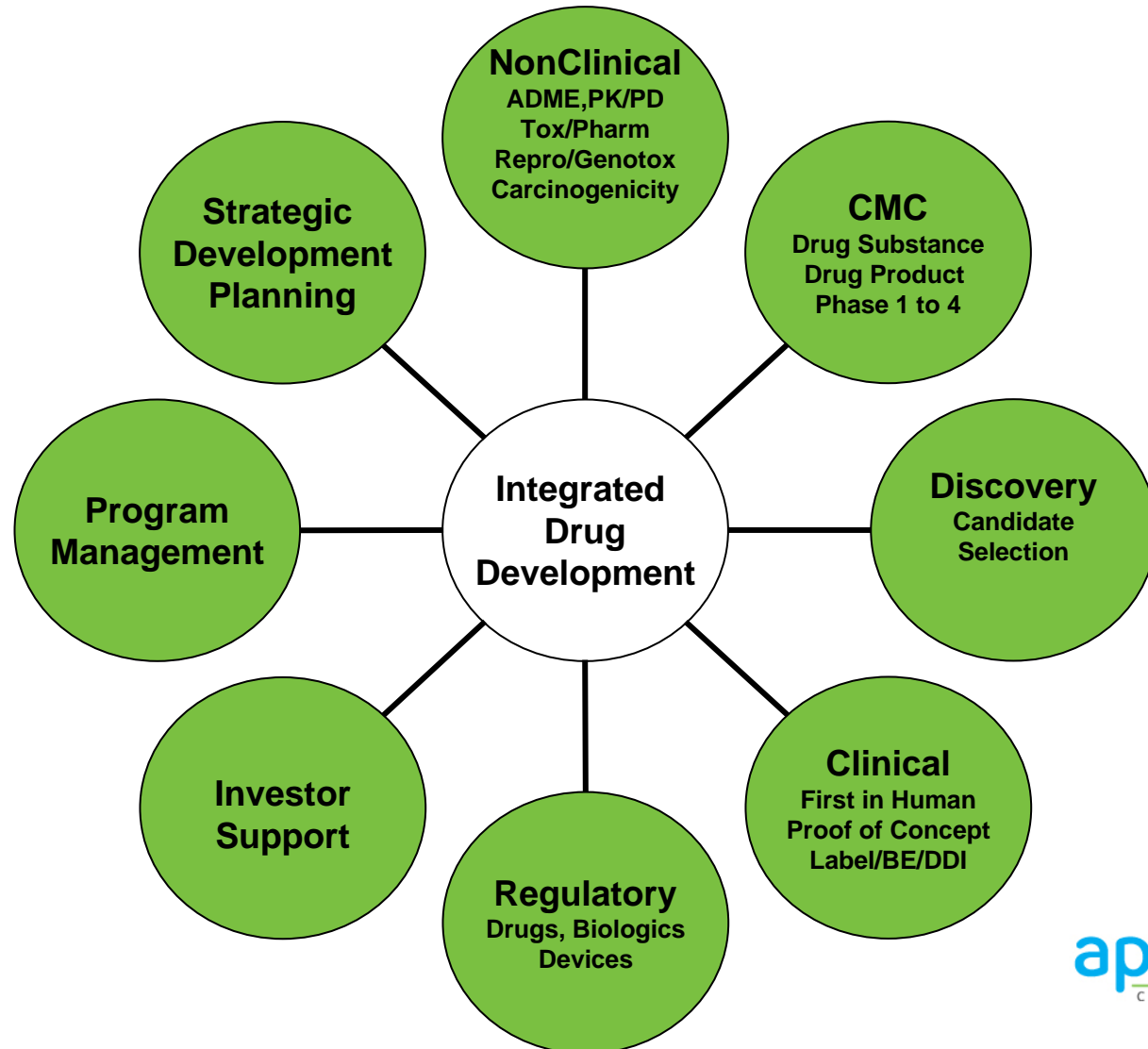
Value Proposition

- Comprehensive capabilities with first-hand experience in large development programs and successful regulatory approvals
- Extensive problem solving skills across all disciplines
- Strong networks

Enable Aptuit Consulting to:

- accelerate development and meet timelines
- minimize risks
- minimize costs and meet budgets
- bring solutions to complex development, regulatory and related challenges or problems

Integrated Service Offering



First-in-Human (FIH) Programs

A streamlined, fully integrated drug development program lead by Aptuit Consulting's Drug Development Experts and Program Managers

Integrated Drug Development

FIH Offerings

- From start of manufacturing
- IND/CTA submission
- Phase 1 SAD/MAD studies
- Cost effective pricing (\$1.5M to \$3.5M)
- Fixed timeline (8-18 months)

FIH Deliverables

- Preclinical and Clinical Trial Material
- Approvable Regulatory Submission
- Phase 0/1 SAD/MAD data

FIH Benefits

- Fully understood pricing
- Fixed timeline
- Regulatory approval

FIH programs executed in pharma and virtual biotechs

Driven by a team of industry-seasoned experts with the infrastructure to deliver on time, on budget, every time

Select Press



**Aptuit Consulting Inc. and Taiwan Liposome Company (TLC)
Collaborate to Complete all IND Enabling Work and IND Submission for
Novel Anti-Cancer Treatment in 12 Months**

***--First Anti-Cancer Drug from Taiwan, Lipotecan[®], to Begin Phase 1
Trial under U.S. IND--***

Aptuit press release, June 25, 2008



Select Press

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