
# Accellient Partners LLC

## Company and Capabilities Overview

# Overview

- Fully integrated and dedicated team of deeply experienced drug development, regulatory and business professionals
- Develop and execute plans to support the strategic, tactical, financial and regulatory-driven product development needs of small biotechnology companies and their investors
- Start, raise funds for and manage new biotech companies
- Efficient development model leverages know-how, information science, eSubmission and business experience
  - minimizing program risks and lowering costs to improve ROI
  - accelerating development timelines via tailored development plans
  - submitting approvable electronic INDs

# Experience

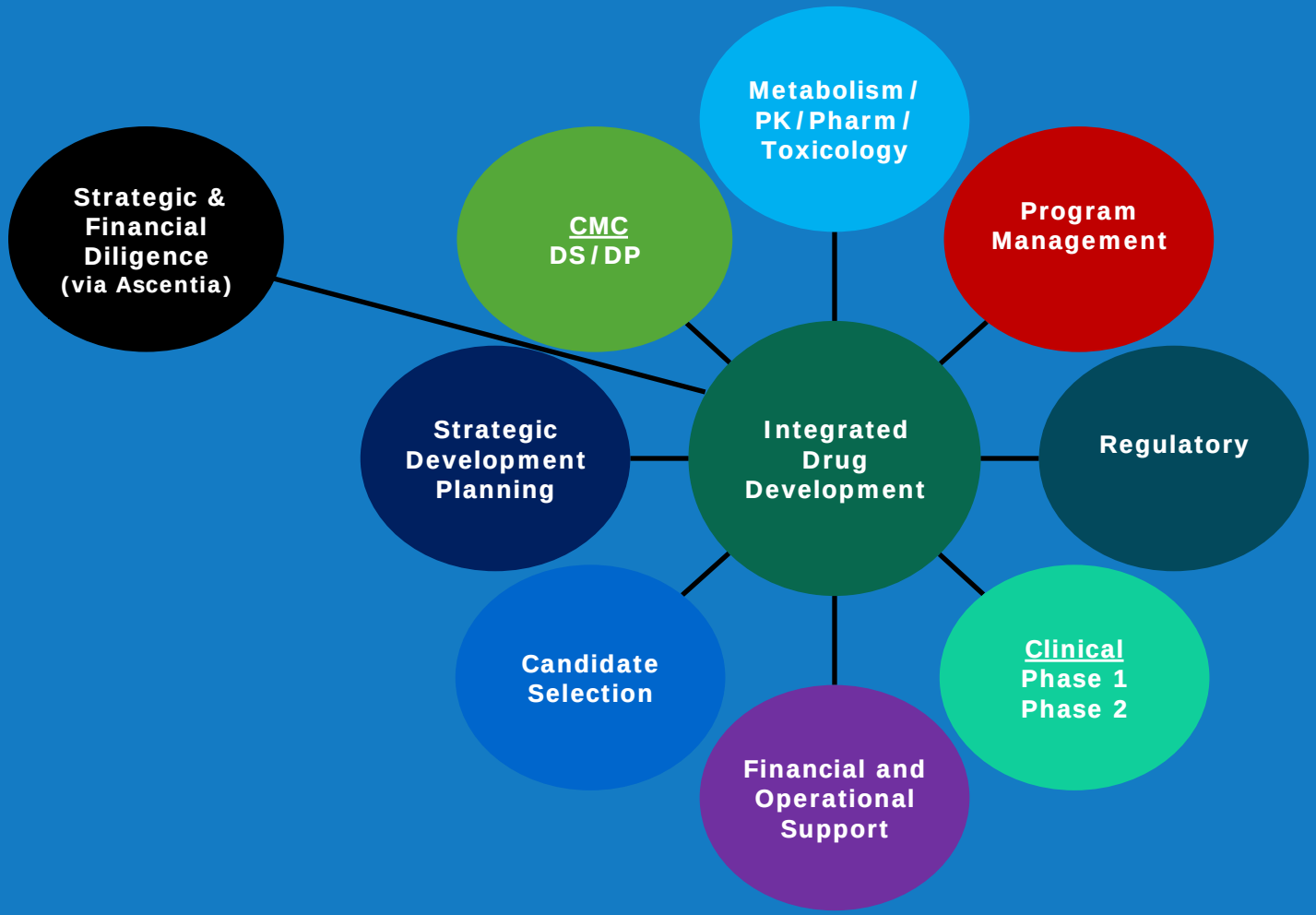
- Therapeutic areas
  - CNS, CV/Renal, Oncology, Respiratory, Rheumatology, Dermal, Anti-infective, Inflammation, Ophthalmology
- Program Types
  - Small molecules, peptides, mAbs, proteins, oligos
- Development Expertise
  - CMC, ADME, Pharmacology, Toxicology, Regulatory, Phase I, Phase II POC
- Submission Experience
  - ~4 IND's each year
  - >200 INDs and 15 NDAs/MAAs
- NuCo Creation and Management
  - Co-found and fund-raise
  - Set-up and manage
  - Launched Synchroneuron and Ternus Pharma

# Service Offering

- Develop and manage programs from late discovery through IND submission, Phase 1 and Phase 2 POC
- Develop and manage 505(b)(2) programs from concept through NDA filing
- Perform gap analyses and due diligence evaluations
- Provide scientific/regulatory solutions in chemistry, formulation, pharmacokinetics, metabolism, toxicology and regulatory
- Create NuCo's and provide executive, scientific and financial management

*Our integrated, yet virtual approach, enables business leaders and investors to defer major human resource investment and infrastructure decisions until they fully understand the risks and probabilities of success*

# Service Area Overview



# First in Human Programs

- Program
  - Manufacturing and formulation development for Toxicology and Phase 1
  - Clinical trial supplies (Capsules, powder in bottle, sterile injectables)
  - Pharmacology/Metabolism/PK/Toxicology
  - Regulatory and approvable IND
  - Phase 1 safety/tolerability/PK study (SAD/MAD)
  - ~$3.5-$5.0M budget
  - 9-18 months
- Deliverables
  - Preclinical and clinical drug substance/drug product
  - Lean preclinical program
  - Approvable regulatory submission
  - Phase 1 SAD/MAD data
- Benefits
  - Budget and timeline supported by decades of experience
  - Approved/Activated IND
  - Phase 1 data delivered on time

*Driven by a team of industry-seasoned experts with the ability to deliver on time almost every time*

# Operational Models

- Time and Materials
  - Hourly fee for service
- Hybrid equity-based risk sharing
- NuCo Creation and Management
  - Synchroneuron Inc.
    - Launched in 2012 (www.synchroneuron.com)
  - Ternus Pharma, Inc.
    - Founded in 2014

# Value Proposition

- Capabilities
  - Possess comprehensive capabilities in chemistry, formulation, pharmacology, toxicology, pharmacokinetics, metabolism, regulatory and early clinical development
- Experience
  - Decades of experience and extensive problem solving skills across multiple disciplines in many therapeutic areas
- Milestone Focus
  - Establish aggressive development plans focused on an in-depth understanding of the science and client/investor milestones
- Networks
  - Leverage a strong network of proven vendors, KOLs and investors
- Results Orientated
  - Deliver approvable projects on time and “right first time”


# Accellient Partners

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