WHITE CROW

INNOVATION, LLC

Pre-clinical Safety to Proof-of-Concept

Mission

Help companies navigate drug development challenges and avoid preventable delays

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Model

- Smooth transition from Discovery to Development
- Providing options to IND
- Biomarkers for decision making
- Achieving proof-of-concept
- Applying 25+ years of drug development experience to advance promising new therapies

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Helping Clients by …

- Bringing background and practical experience on the realities of drug development
- Providing options that achieve key milestones
- Reducing time lines through integrated study designs and customized approaches
- Proactively identifying regulatory considerations
- Connecting companies with CROs, specialized laboratories, and academic researchers

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Areas of Expertise

- Synthetic proteins/peptides, combination molecules, biologics, small molecules, gene therapy
- Oncology, inflammation, autoimmunity, CNS, pain, cardiovascular, metabolic disease, and anti-infectives
- Successfully aided multiple molecules (including Lipitor, Lyrica, Lopid, and Neurontin) to market
- Collaborating with internal and external groups to efficiently achieve development milestones

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Increasing Speed & Decreasing Costs

- "Renting" drug development expertise rather than hiring & training internal personnel
- Complementing virtual biotech organizations
- Early integration of clinical design & preclinical plan
- Translational & personalized medicine approaches
- Matching of company with compatible CROs
- Pre-IND discussions to vet novel approaches

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Michael R. Bleavins, Ph.D., DABT

- Toxicology/laboratory medicine
- 6 years consulting for biotechs
- 19 years at Parke-Davis/Warner-Lambert/Pfizer
- Pre-clinical to clinical bridging
- Translational medicine
- Biomarkers and assay validation
- Author of >60 publications
- Adjunct faculty at University of Michigan & Wayne State University

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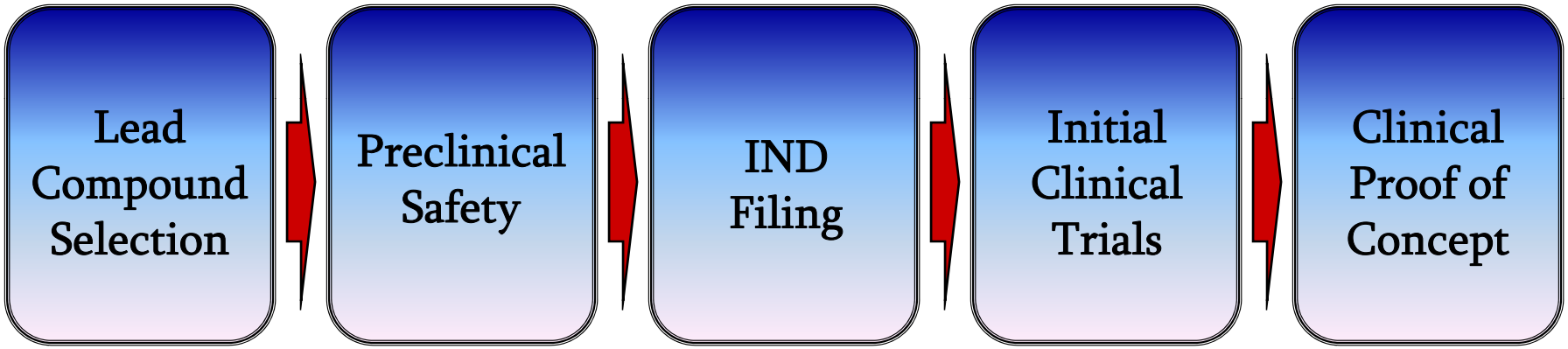
Key Goals of Development

Helping integrate and optimize the process



- Target identification
- Molecule optimization
- Predictive pharmacology

- Predictive toxicology
- Toxicokinetics and exposures
- ”Safe” initial clinical dose

- SAFETY!
- Tolerance
- Target interaction
- Metabolism/PK
- Activity
- Drug interactions

- Safety
- Proof-of-concept
- Therapeutic dose selection
- Characteristics

- Efficacy
- Safety
- Broad patient experience
- Therapeutic considerations

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Identifying the Best Drug Candidate

Lead Compound Selection

- Compound prioritization
- Salt selection
- Formulations
- Screening safety tests
- Novel development options
- *In vitro* metabolism
- Analytical considerations
- Pharmacology
- Pharmacokinetics
- Biomarker identification

White Crow offers:

- Compound specific drug plans
- Ideas on screening approaches to choose successful molecules
- Early identification of safety or clinical considerations
- Targeted designs to identify & resolve efficacy/safety questions
- Leveraging pharmacology testing to enhance preclinical safety studies & time lines

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Defining Safe Starting Doses

Preclinical Safety

- Integrated strategy
- Study design & monitoring
- GLP expertise
- Report review
- Safety assessment
- Biomarker development
- Mechanistic studies
- Project & risk management
- Compliance with regulatory agency requirements

White Crow provides:

- A partner in navigating the GLP drug development process
- Bridging strategies to shorten time lines and enhance regulatory agency interactions
- Study design, CRO bidding, and monitoring of GLP safety studies
- Report review and relevance
- Biomarker applications that enhance decision making

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Regulatory Agency Interactions

IND Filing

- Novel strategies for biologics and small molecules
- Early assessment of activity
- Pre-IND meetings
- Agency briefing documents
- Safety assessments
- Literature reviews
- Investigator brochure
- Initial clinical plan
- Report tracking systems

White Crow can help:

- Design safety paths to IND, including customized approaches where route forward is unclear
- Differentiate between regulatory guidance and requirements to conduct most appropriate testing
- Prepare regulatory safety documents and assist in pre-IND meetings
- Put toxicity findings into perspective with scientifically-based risk assessments

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Getting to First-in-Human Studies

Initial Clinical Trials

- Defining safety considerations
- Estimation of starting dose
- Assisting in clinical trial design
- Patient/volunteer trials
- CRO selection
- Working with CRO
- Biomarker identification
- Biomarker assay development
- Genotyping

White Crow provides:

- Options for challenging therapies/alternative indications
- Translational medicine expertise for efficacy & toxicity
- Assistance in integrating genetic testing into clinical trials
- Biomarker strategies for early activity determination
- Identification and qualification of reference laboratories

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Demonstrating Efficacy

Clinical Proof of Concept

- Novel patient selection
- Biomarker identification
- Biomarker development
- Genetic patient stratification
- Non-routine data interpretation
- Safety considerations
- Sample processing

White Crow enhances:

- Use of decision-making biomarkers to stratify patients and confirm indications
- Non-traditional approaches to assess activity/efficacy/safety
- Data interpretation/relevance for non-traditional tests
- On-site training of laboratory technologists in specialized tests
- Interactions with IRBs when including genetic testing

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Other Services

- Report writing and report tracking systems
- Coaching of internal staff in writing regulatory filings and response documents
- Training sessions in drug development, translational medicine, exploratory IND approaches, and biomarkers
- Differentiating species-specific safety consideration from human risk
- Pharmacogenetic options and considerations

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Why Choose White Crow Innovation?

- Optimized time lines and efficient use of capital
- Drug develop plans customized to your molecule
- Experienced partner in drug development and regulatory interactions
- Integrated options from lead compound selection to clinical proof-of-concept
- Complementing of company's internal resources or full responsibility for drug development support
- Proven track record of getting drugs to key milestones

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Typical Clients

Biotechnology

- Small molecule, biologic, synthetic peptide/protein, hybrid molecule, or novel first-in-class molecule/platform
- Transitioning from drug discovery to drug development
- Virtual or brick & mortar organization

Academic Institution

- Cutting-edge research group
- Novel drug platform or new approach
- Need to move outside university approaches to drug development

Medium to Large Pharmaceutical

- Late- stage compound in trouble & needing mechanistic options
- Integration of novel biomarker or genetic testing

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Contact Information

Michael R. Bleavins, Ph.D., DABT

White Crow Innovation, LLC

7444 Dexter-Ann Arbor Road, Suite E-2

Ann Arbor, MI 48130

734.904.0020

Mike@White-Crow-Innovation.com

www.White-Crow-Innovation.com

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