DEVELOPMENT PROGRAM FOR SMALL MOLECULES

DISCOVERY PRECLINICAL CLINICAL PHASE I PHASE II PHASE III Approval

DISCOVERY: We conduct *in vitro* and *in vivo* studies for lead optimization to screen your chosen compounds for toxicology, safety pharmacology, metabolites, and other safety assessments to meet regulatory and scientific milestones. In addition, our Bioanalysis & Research Services provide additional support throughout development.

COLOR KEY: Nonclinical Clinical Currently Not Available at Altasciences

ENTRY IN HUMAN

Dose Ranging Studies

Efficacy X2

- Lead Optimization Studies
- Metabolite Screens
- Metabolites (Animal and Human)
- Primary/Secondary PD
- DDI / TDI Screens
- First-in-Human SAD and MAD
- Proof of Concept
- ADME
- Thorough QT
- Bioavailability
- Human Abuse Potential
- Drug-Drug Interaction
- Drug-Drug Interaction #2
- Bioequivalence
- Food-Effect Pilot
- Drug-Drug Interaction #3
- PK Special Population
- Renal Impaired
- Food-Effect Definitive
- Hepatic Impaired
- Animal ADME
- Primary/Secondary PD
- Drug-Drug Interactions / Time-Dependent Inhibition
- Drug Alcohol
- Driving Simulation
- Toxicology / Safety Pharmacology Screens
- Protein Binding
- qWhole Body Autoradiography
- Milk Secretion
- Subacute Rodent Repeated Dose Toxicity
- Subchronic Rodent Repeated Dose Toxicity
- Chronic Rodent Repeated Dose Toxicity
- Rodent DRF
- Non-Rodent DRF
- Subacute Non-Rodent Repeated Dose Toxicity
- Subchronic Non-Rodent Repeated Dose Toxicity
- Chronic Non-Rodent Repeated Dose Toxicity
- Local Tolerance
- Animal HAP
- Safety Pharmacology
- Genotox
- Rodent/Non-Rodent Reproductive Toxicology
- Carcinogenicity

BIOANALYSIS INCLUDING BIOMARKERS

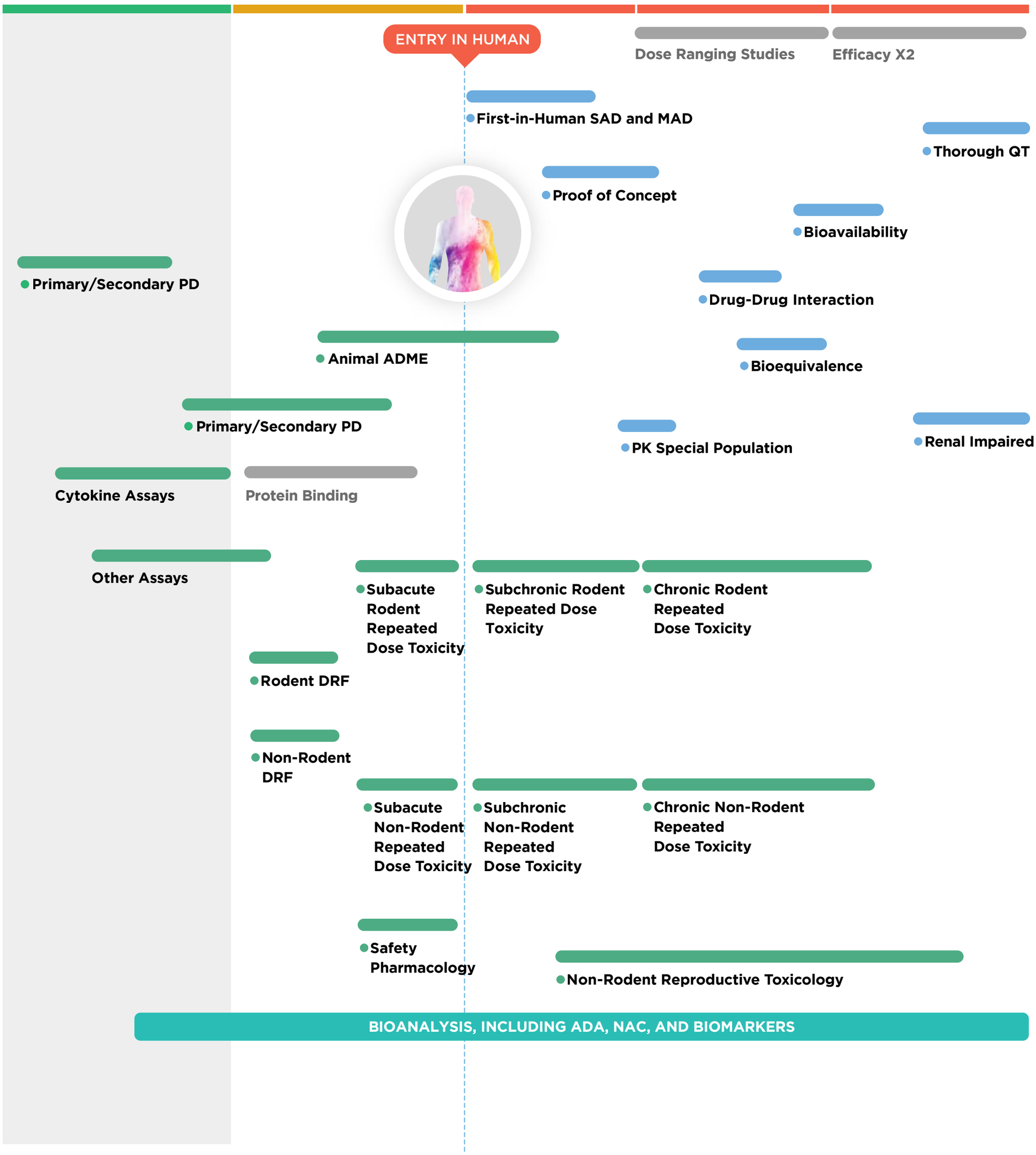
This chart is not to scale and reflects one example of a development path and sequence followed; actual sequence, length and types of studies may vary based on indication, molecule and program needs. All development programs need to be customized depending on the molecule, mechanism of action and indication. However, for biologics the studies required for each program differs to an even greater extent due to the need for relevant models and the ADME for biologics being so different than small molecules. Please **Contact us** to learn more about the different requirements.

DEVELOPMENT PROGRAM FOR BIOLOGICS

DISCOVERY PRECLINICAL CLINICAL PHASE I PHASE II PHASE III Approval

DISCOVERY: We conduct *in vitro* studies for primary and secondary pharmacodynamics as well as cytokine and other assays to meet regulatory and scientific milestones. Our *in vivo* immunogenicity studies and Bioanalysis & Research Services provide additional support throughout.

COLOR KEY: Nonclinical Clinical Currently Not Available at Altasciences



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DEVELOPMENT PROGRAM FOR SMALL MOLECULES

DISCOVERY | **PRECLINICAL** | CLINICAL PHASE I | PHASE II | PHASE III | Approval

PRECLINICAL: Our Preclinical Services include pharmacodynamics, DRF/MTD, and subacute repeated dose toxicity studies in rodent and non-rodent species to move your program toward clinical trials and then as it progresses towards regulatory submission.

COLOR KEY: Nonclinical | Clinical | Currently Not Available at Altasciences

ENTRY IN HUMAN

- Lead Optimization Studies
- Metabolite Screens
- Metabolites (Animal and Human)
- Primary/Secondary PD
- DDI / TDI Screens
- Animal ADME
- First-in-Human SAD and MAD
- Proof of Concept
- Dose Ranging Studies
- Efficacy X2
- ADME
- Thorough QT
- Bioavailability
- Human Abuse Potential
- Drug-Drug Interaction
- Drug-Drug Interaction #2
- Bioequivalence
- Food-Effect Pilot
- Drug-Drug Interaction #3
- PK Special Population
- Renal Impaired
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- Safety Pharmacology
- Genotox
- Rodent/Non-Rodent Reproductive Toxicology
- Carcinogenicity
- BIOANALYSIS INCLUDING BIOMARKERS

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DEVELOPMENT PROGRAM FOR BIOLOGICS

DISCOVERY **PRECLINICAL** CLINICAL PHASE I PHASE II PHASE III Approval

PRECLINICAL: Our Preclinical Services include *in vivo* pharmacodynamics, animal ADME, DRF/MTD, and subacute repeated dose toxicity studies in rodent and non-rodent species to move your program toward clinical trials.

COLOR KEY: Nonclinical Clinical Currently Not Available at Altasciences

ENTRY IN HUMAN

Dose Ranging Studies

Efficacy X2

First-in-Human SAD and MAD

Thorough QT

Proof of Concept

Bioavailability

Primary/Secondary PD

Drug-Drug Interaction

Animal ADME

Bioequivalence

Primary/Secondary PD

PK Special Population

Renal Impaired

Cytokine Assays

Protein Binding

Other Assays

Subacute Rodent Repeated Dose Toxicity

Subchronic Rodent Repeated Dose Toxicity

Chronic Rodent Repeated Dose Toxicity

Rodent DRF

Non-Rodent DRF

Subacute Non-Rodent Repeated Dose Toxicity

Subchronic Non-Rodent Repeated Dose Toxicity

Chronic Non-Rodent Repeated Dose Toxicity

Safety Pharmacology

Non-Rodent Reproductive Toxicology

BIOANALYSIS, INCLUDING ADA, NAC, AND BIOMARKERS

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DEVELOPMENT PROGRAM FOR SMALL MOLECULES

DISCOVERY | PRECLINICAL | **CLINICAL PHASE I** | PHASE II | PHASE III | Approval

PHASE I: Altasciences is a recognized leader in conducting first-in-human, proof of concept, and related studies in both healthy normal volunteers and patient populations. We also conduct nonclinical subchronic repeated dose toxicity studies in rodent and non-rodent species that complement early phase clinical drug development.

COLOR KEY: Nonclinical | Clinical | Currently Not Available at Altasciences

ENTRY IN HUMAN

- Lead Optimization Studies
- Metabolite Screens
- Metabolites (Animal and Human)
- Primary/Secondary PD
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- Subchronic Non-Rodent Repeated Dose Toxicity
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- Animal HAP
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Safety Pharmacology

Non-Rodent Reproductive Toxicology

BIOANALYSIS, INCLUDING ADA, NAC, AND BIOMARKERS

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DEVELOPMENT PROGRAM FOR SMALL MOLECULES

DISCOVERY | PRECLINICAL | CLINICAL PHASE I | **PHASE II** | PHASE III

Approval

PHASE II: Our Clinical Services include all the clinical pharmacology studies to provide the data to advance you compound through Phase II. We also conduct nonclinical chronic repeated dose toxicity studies in rodent and non-rodent species, to complement your clinical drug development.

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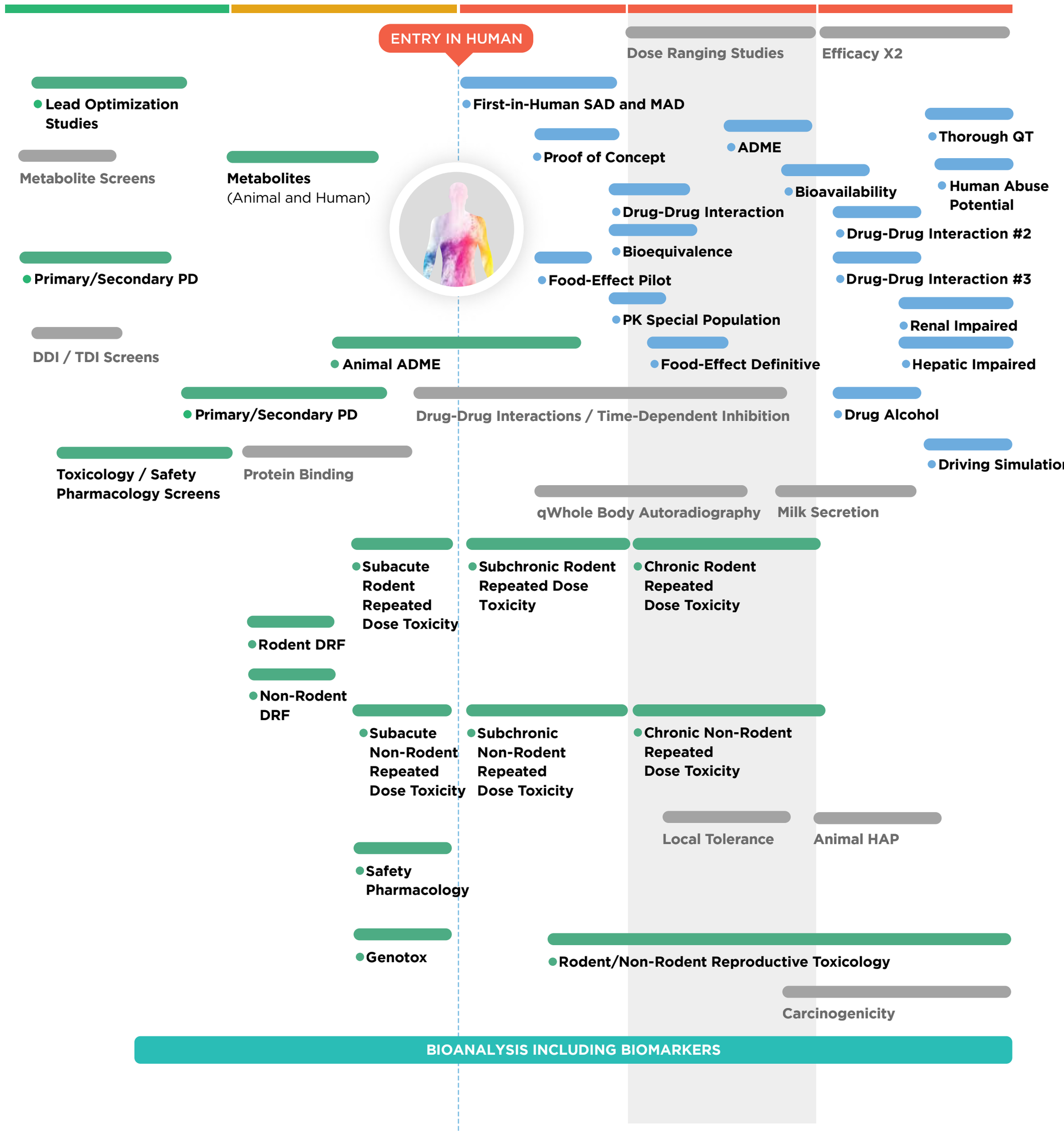

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DEVELOPMENT PROGRAM FOR BIOLOGICS

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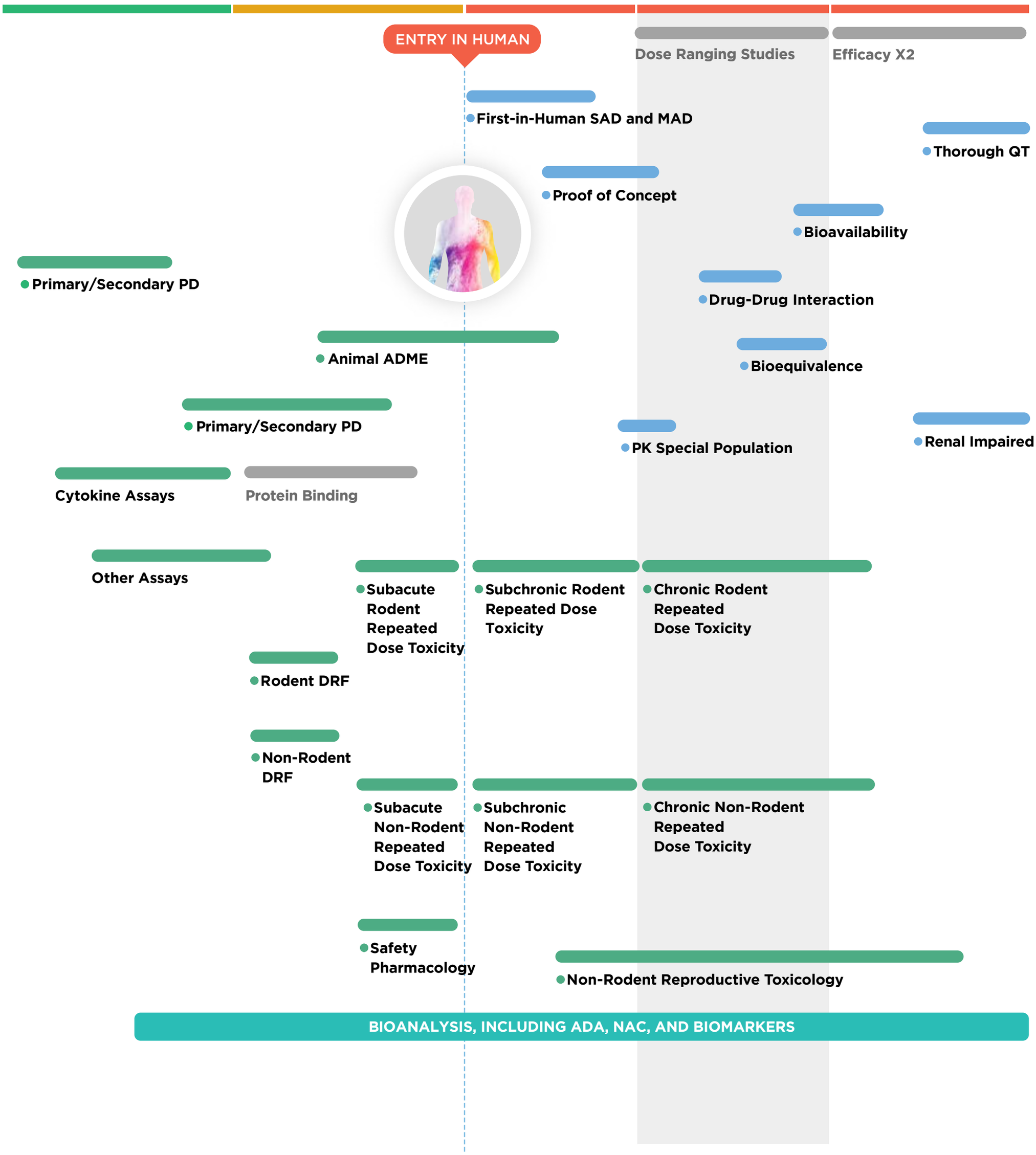

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DEVELOPMENT PROGRAM FOR SMALL MOLECULES

DISCOVERY | PRECLINICAL | CLINICAL PHASE I | PHASE II | **PHASE III** | Approval

PHASE III: As your test article undergoes Phase III efficacy studies elsewhere, we support its development through clinical studies ranging from drug-drug interaction, renal or hepatic impaired, QT assessments, and, as needed, drug-alcohol interaction, human abuse potential, and driving simulation. We also conduct a range of critical nonclinical studies in rodent and non-rodent species including reproductive toxicology.

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ENTRY IN HUMAN

- Lead Optimization Studies
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- BIOANALYSIS INCLUDING BIOMARKERS

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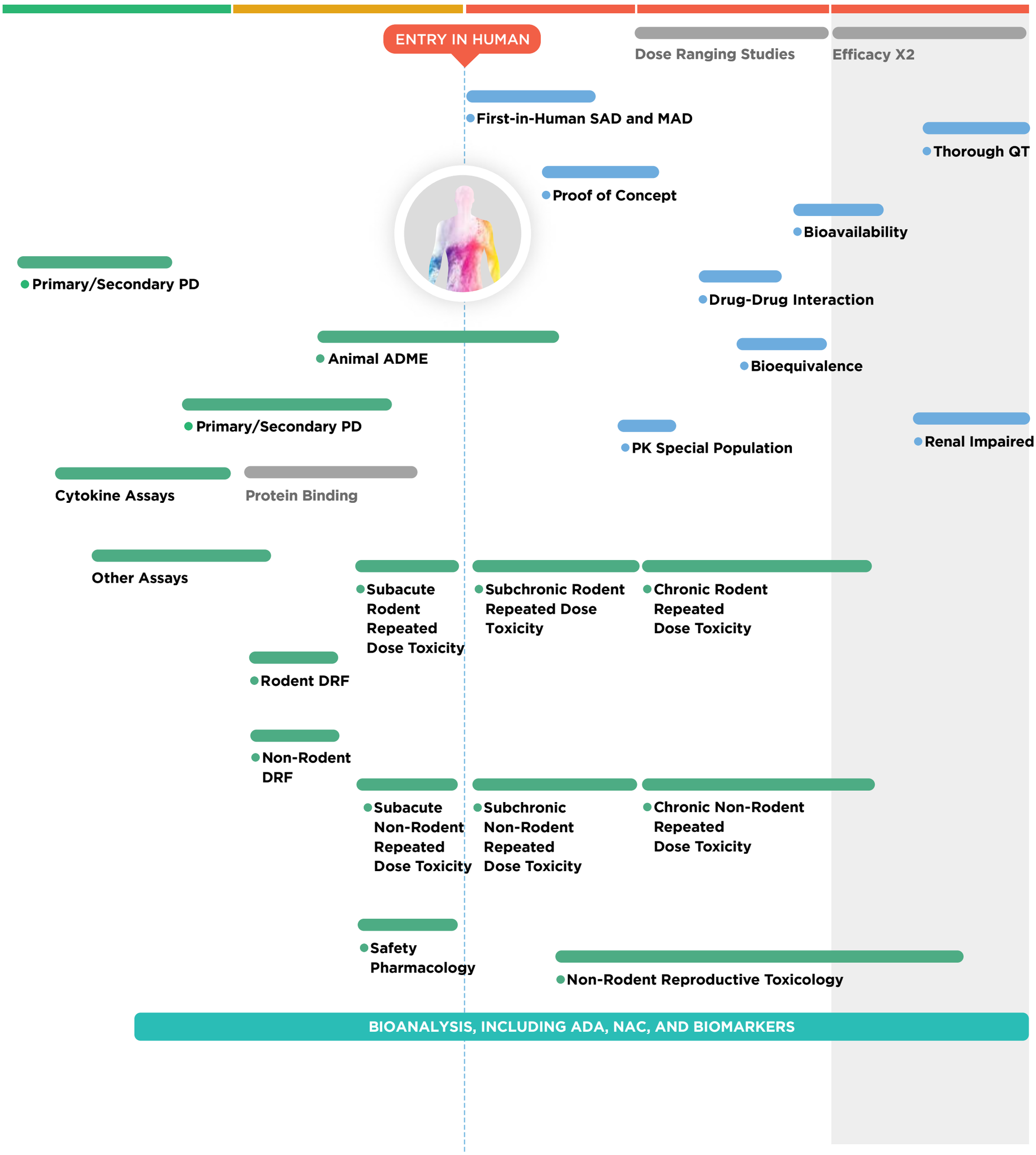
DEVELOPMENT PROGRAM FOR BIOLOGICS

DISCOVERY | PRECLINICAL | CLINICAL PHASE I | PHASE II | **PHASE III** | Approval

PHASE III: As your biologic undergoes Phase III efficacy studies elsewhere, we support its development through all the clinical pharmacology studies that are required. We also conduct nonclinical reproductive toxicology studies in non-rodent species.

COLOR KEY: Nonclinical | Clinical | Currently Not Available at Altasciences



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