Preclinical Development of Biologics at WuXi AppTec

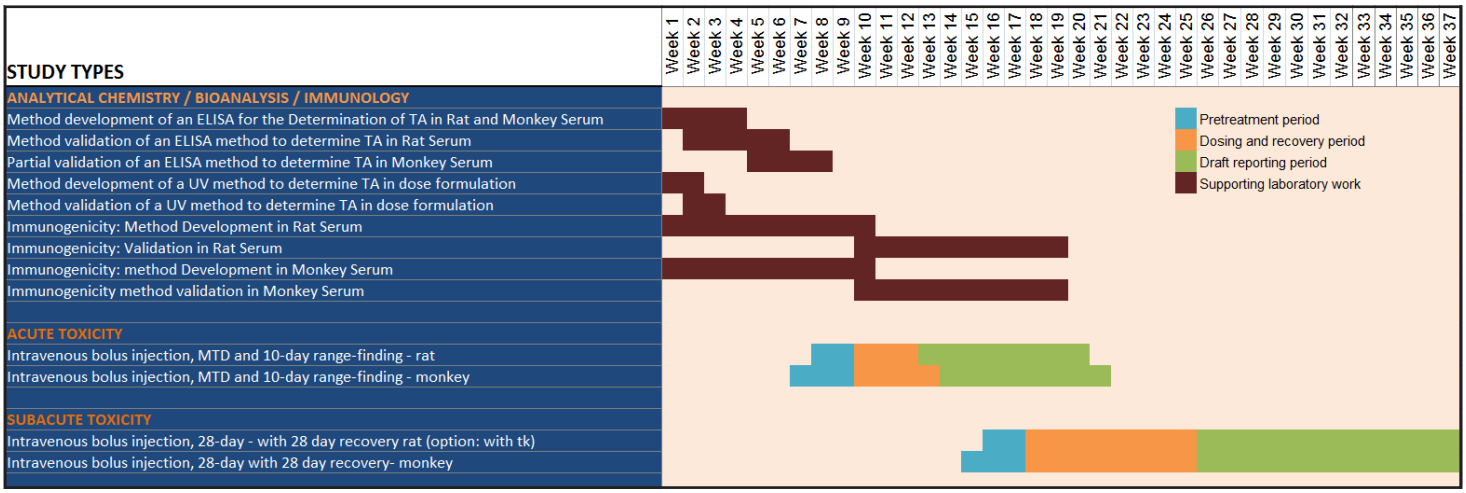
Guidance for preclinical safety assessment of biotechnology-derived pharmaceuticals has recently been updated with the revised ICH S6 (R1) reaching Step 4 in June 2011. At WuXi AppTec, our integrated service platform for biologics development includes extensive capabilities to meet the requirements of this guideline, in line with our goal to help our worldwide customers shorten the time and lower the cost of R&D through cost-effective and efficient outsourcing solutions.

Species Selection for Preclinical Studies

WuXi AppTec's capabilities for in vitro assays and in vivo biology can help determine the relevant animal species for preclinical studies. In addition, tissue cross-reactivity assays with both human and animal tissues are available where needed to provide further guidance. Usually the non-human primate will be pharmacologically relevant species for biologics development and WuXi AppTec maintains colonies of Cynomolgus non-human primates at several AAALAC-accredited suppliers in China to minimize delays in obtaining animals and study starts.

Preclinical Study Capabilities

WuXi AppTec has extensive experience in non-human primate PK studies as well as general toxicity studies up to 6 months duration, as per the requirements of the revised ICH guidance, including dosing via intravenous infusion in rodents and non-rodents. Molecules include monoclonal antibodies, vaccines, peptides and other proteins. Supplemental studies such as safety pharmacology can be included in general toxicology study designs or as individual projects, depending on the nature of the test article. Fully GLP-compliant analytical support available include analytical and bioanalytical method development and validation, and assessment of a test compound's potential immunogenic or immunotoxic effects.



NOTE: Timelines are for illustration purposes only and are customized to each program

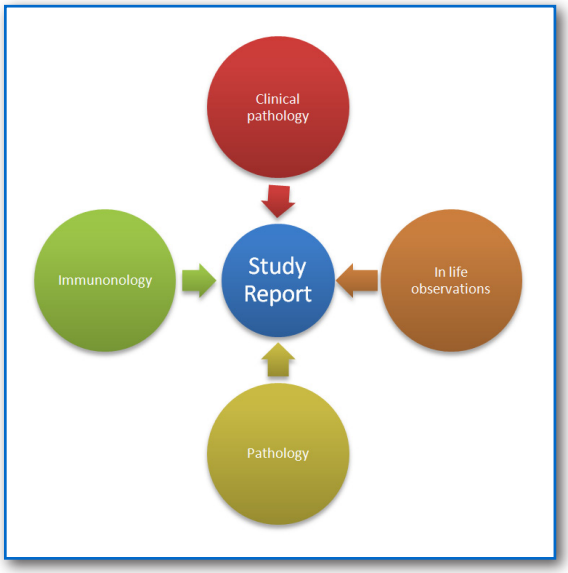
The above is a standard program for a biologic when administered intravenously for an IND submission to support clinical trials in the USA for up to 1 month. Each program is reviewed individually and modified to accelerate timelines based on a client's requirements.

As the only AAALAC-accredited CRO in the world to receive a statement of GLP compliance from OECD (Belgium) and a certificate of GLP compliance from SFDA (State Food and Drug Administration), WuXi AppTec helps our partners accelerate their timelines at a significant cost advantage of up to 50% savings for Biologic programs.

WuXi AppTec Preclinical Services supporting Biologics

Immunology Services

- TCR/Immunohistochemistry
- Immunochemistry
- Flow Cytometry



Toxicology Services

Our preclinical studies for biologics are customized for each product and designed to generate meaningful results through the performance of a thorough scientific and regulatory-compliant program.

- FDA, OECD, SFDA Good Laboratory Practice (GLP) compliant
- Complete range of studies:
  - PK studies
  - Dose-range finding or MTD studies
  - Single dose (acute toxicity) studies
  - Repeat dose (sub-acute, sub-chronic and chronic) studies

WuXi AppTec's scientific team has experience in assisting our sponsors with program requirements for preclinical development of biologics by helping to design repeat toxicology studies in both rodents and non-human primates based on the product's mechanism of action, and incorporating aspects such as the biologics clinical dosing route and regimen. Study designs may typically be enhanced with pharmacodynamic and immunogenicity analyses, local tolerance evaluation (Draize measurement), and immunomodulating assessment via KLH challenge (TDAR). WuXi AppTec's laboratories are equipped for in-house analyses of biologics and biomarkers. Robust toxicology designs are available for rapid safety assessment of biosimiliars, minimizing the time to clinical trials.

Other services available:

- Analytical Chemistry – method development, validation and sample analysis
- Safety Pharmacology – CNS, respiratory and cardiovascular, hERG
- Anatomic and Clinical Pathology

Why Choose WuXi AppTec ?

Fully integrated Services:	✓Integrated quotation, contract, logistics and invoice process across WuXi to shorten the overall processing time
	✓ Fully integrated services within WuXi accelerate timelines
Management/Staff:	✓ Dedicated management with over 150 combined years of experience in the preclinical industry
	✓ Multi-disciplinary scientific expertise including western trained staff
Facility:	✓ Full AAALAC accreditation
	✓ **Only facility in the world to have statement of GLP compliance from OECD member country (Belgium) and GLP certification from China SFDA**
	✓ **Large NHP capacity – quick start lead in time to start NHP studies from date of authorization**
	✓ Logistics support for import and export of test article/biological samples
Regulatory Filing:	✓ Fully compliant with FDA, OECD and SFDA GLP requirements
	✓ Assist clients with study and program design for global filing
Cost Saving:	✓ **Potential for up to 50% cost savings over US study costs for biologics programs**
	✓ Global IND filing capability to enable additional cost saving and shorten drug development timeline
Customer Responsiveness:	✓ Rapid turnaround and flexibility
	✓ Focus on communication and on time reporting of study data and report

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