

MRIGlobal – Centralized Chemopreventive Agent Repository Support

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Introduction and Overview

MRIGlobal

- An independent, not-for-profit research organization founded in 1944 working in pharmaceutical development, life sciences, national security, and energy research
- Providing support to the NCI for over 50 years
- Currently operating the NCI DCP Repository to support clinical and preclinical programs

Pharmaceutical Sciences

VISION

- Use our innovative teams to deliver quality, research-based solutions

STRATEGIC FOCUS

- Pharmaceutical Sciences is the keystone of our preclinical and clinical support services. Complimentary services include disease diagnostics, toxicology, and life science support



MRIGlobal History



Locations in 3 States
Plus Managed Facilities and International Programs

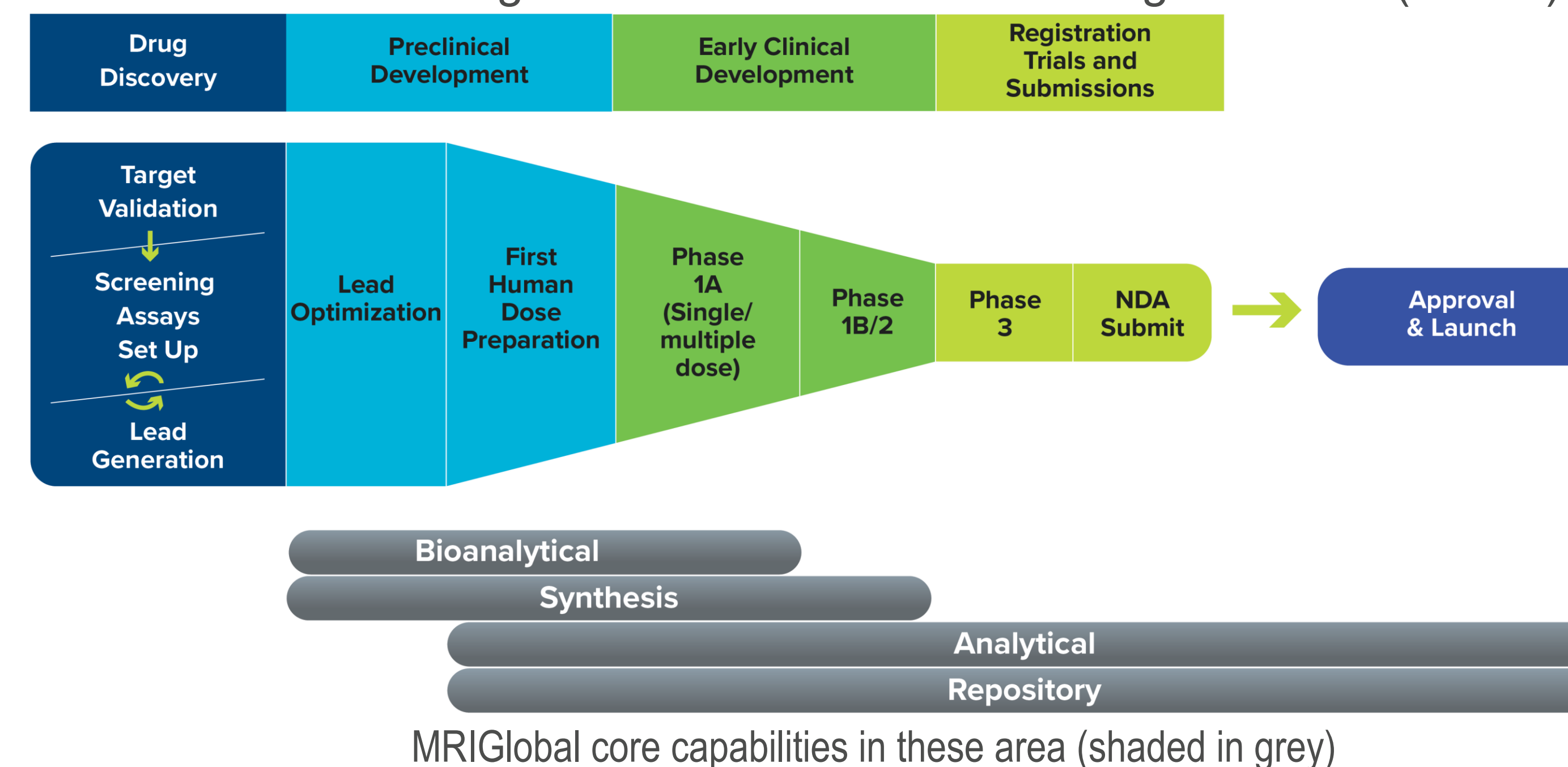
MRIGlobal Headquarters

Kansas City, MO
245,000 sq. ft.

MRIGlobal Pharmaceutical Services

MRIGlobal provides comprehensive support services starting from agent procurement to receipt, storage and distribution for preclinical and clinical studies. Some examples include:

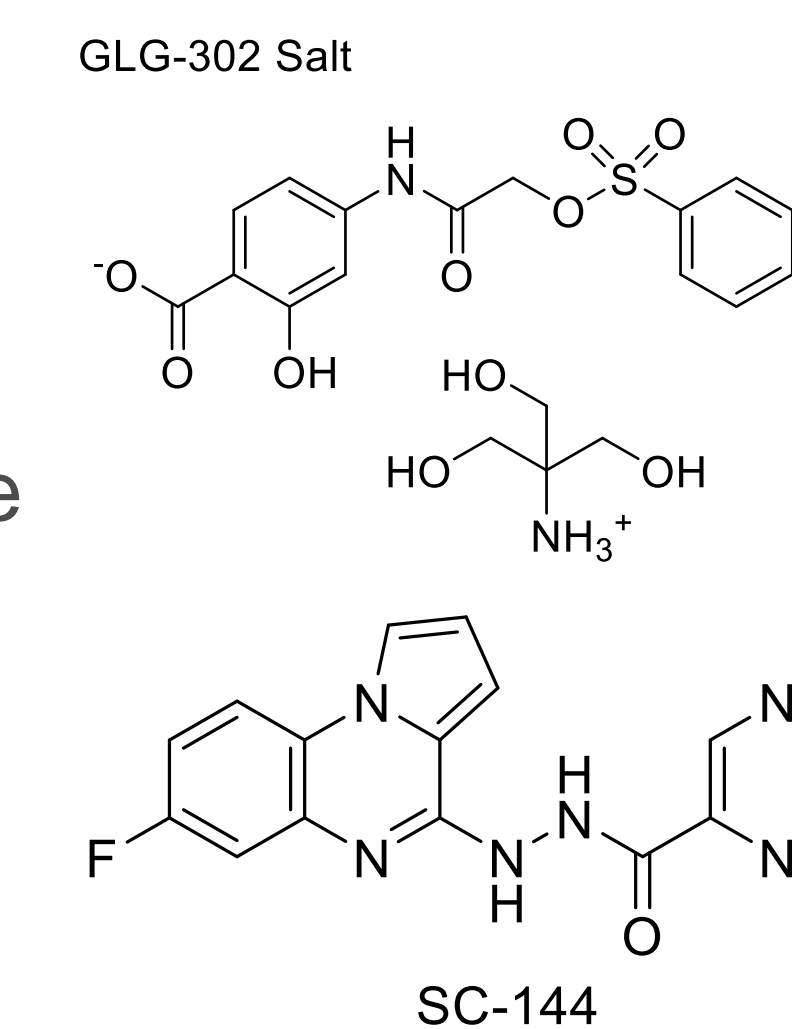
- Preclinical material procurement or production in-house
 - Synthesis, formulation, and cGMP manufacturing for APIs and drug products
- Analytical support testing is performed on-site
 - Analytical method development, validation and stability testing in accordance with ICH guidelines
- Clinical trial material packaging and labeling along with storage and distribution adhering to FDA's Good Manufacturing Practices (cGMP)



Cancer Prevention Agent Development Examples

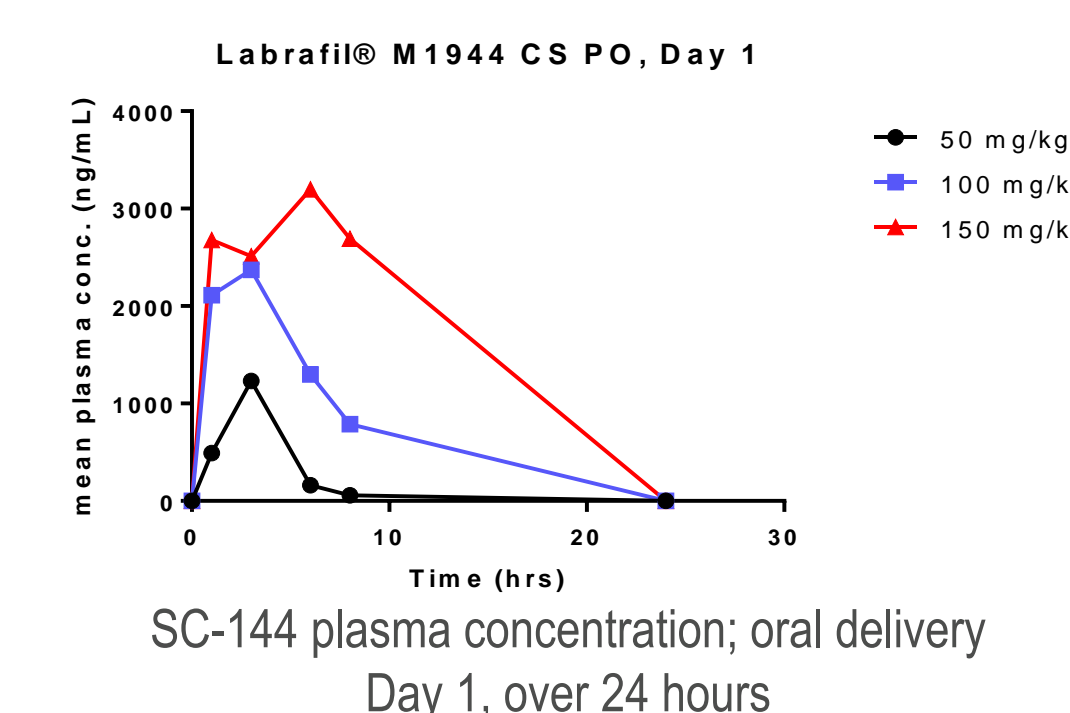
GLG-302 formulation development

- GLG-302 is under investigation as an inhibitor of STAT3.
- As a lipophilic drug with poor aqueous solubility, formulation development was carried out to enable preclinical use. Through program efforts, a unique salt making use of tromethamine was developed.



SC-144 formulation development

- SC-144, a quinoxaline hydrazide with IL-6 signal transducer/gp130 inhibitory activity is under development.
- As a lipophilic, water insoluble compound, a novel formulation containing lipid, surfactant and co-surfactants was developed to support preclinical study through the NCI.
- PK studies were conducted to compare various formulations.



Cancer Prevention Agent Development Examples

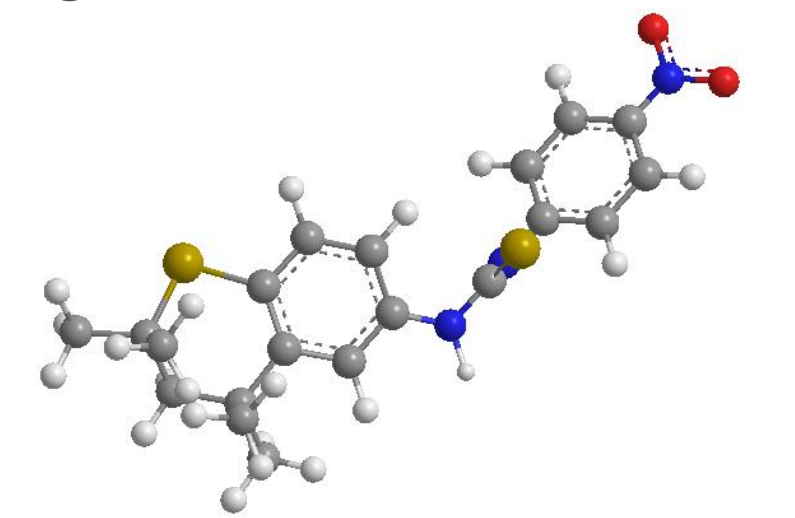
Endoxifen Topical cGMP Manufacturing

- cGMP drug product manufacturing of a topical gel was carried out
- Bottling, labeling, and kit preparation followed by clinical distribution
- Agent was used in a Phase I clinical trial (NWU2017-09-01)



SHetA2

- Heteroarotinoid under development by OUHSC. MRIGlobal was requested to generate cGMP API and cGMP drug product.
- To date, 1 kg of cGMP drug product was produced using a 5-step synthesis route.
- cGMP drug product manufacturing was completed following an OUHSC procedure to generate ~10,000 capsules for Phase I use



Solution Focused

MRIGlobal recognizes the challenges associated with providing preclinical and clinical support

- Solutions-focused to meet timelines, scope objectives and budget
- Clear communication
- Robust supply chain management
- Quality with rigorous adherence to FDA requirements



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The science you expect. The people you know.

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