Creation of a Shared Database for Animal Model Information

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INTRODUCTION

The Alliance for Biosecurity is a consortium of pharmaceutical and biotechnology companies, and the Center for Biosecurity of the University of Pittsburgh Medical Center. The Alliance's mission is to partner with government to accelerate development of medical countermeasures (MCMs) for bioterror agents and emerging infectious diseases.

The Alliance's Animal Model Working Group is creating a shared database that will serve (i) as a resource for scientists and (ii) contain data and summaries from animal model development studies related to therapeutic countermeasures for various high priority biothreats. As a first step, the Group is developing a prototype database that will contain natural history and control data from New Zealand White rabbits and non-human primate studies related to development of anthrax therapies. The prototype will be used to demonstrate the concept and refine database user requirements. It will be expanded into a mature database that will contain data relevant to other biothreats such as plague, tularemia, etc.

IMPETUS and VISION

Current animal model development efforts are fragmented, inefficient, and duplicative. Information (successes, failures) is not shared among stakeholders.

A database will increase sharing of information collected on animal model development issues so that FDA, BARDA, NIH, DOD, companies, research centers, and other stakeholders can more quickly achieve the end goal of developing effective MCMs, (Figure 1).
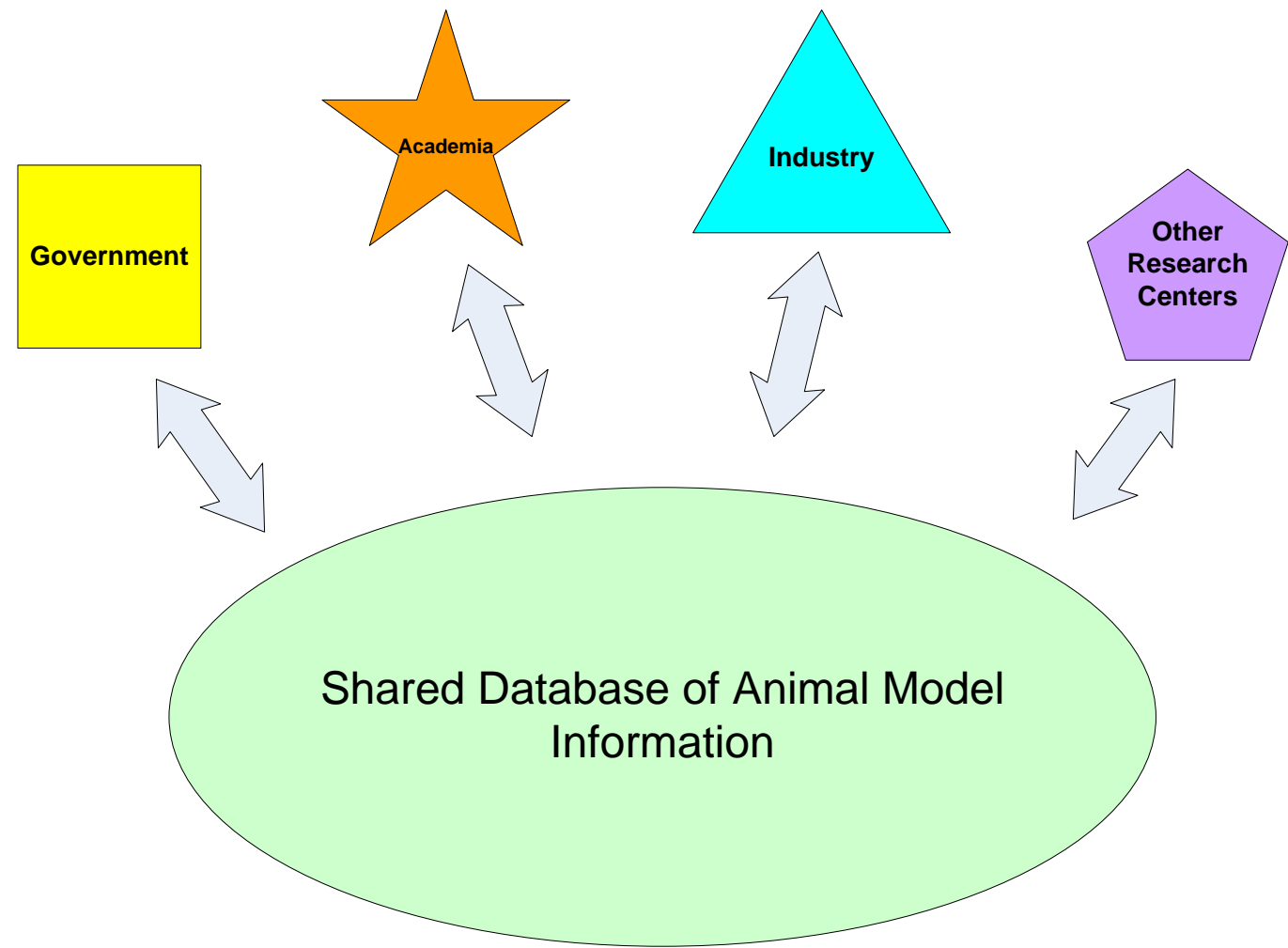

Figure 1. A database of animal model information would serve as a central repository and would increase data sharing and efficiencies among stakeholders
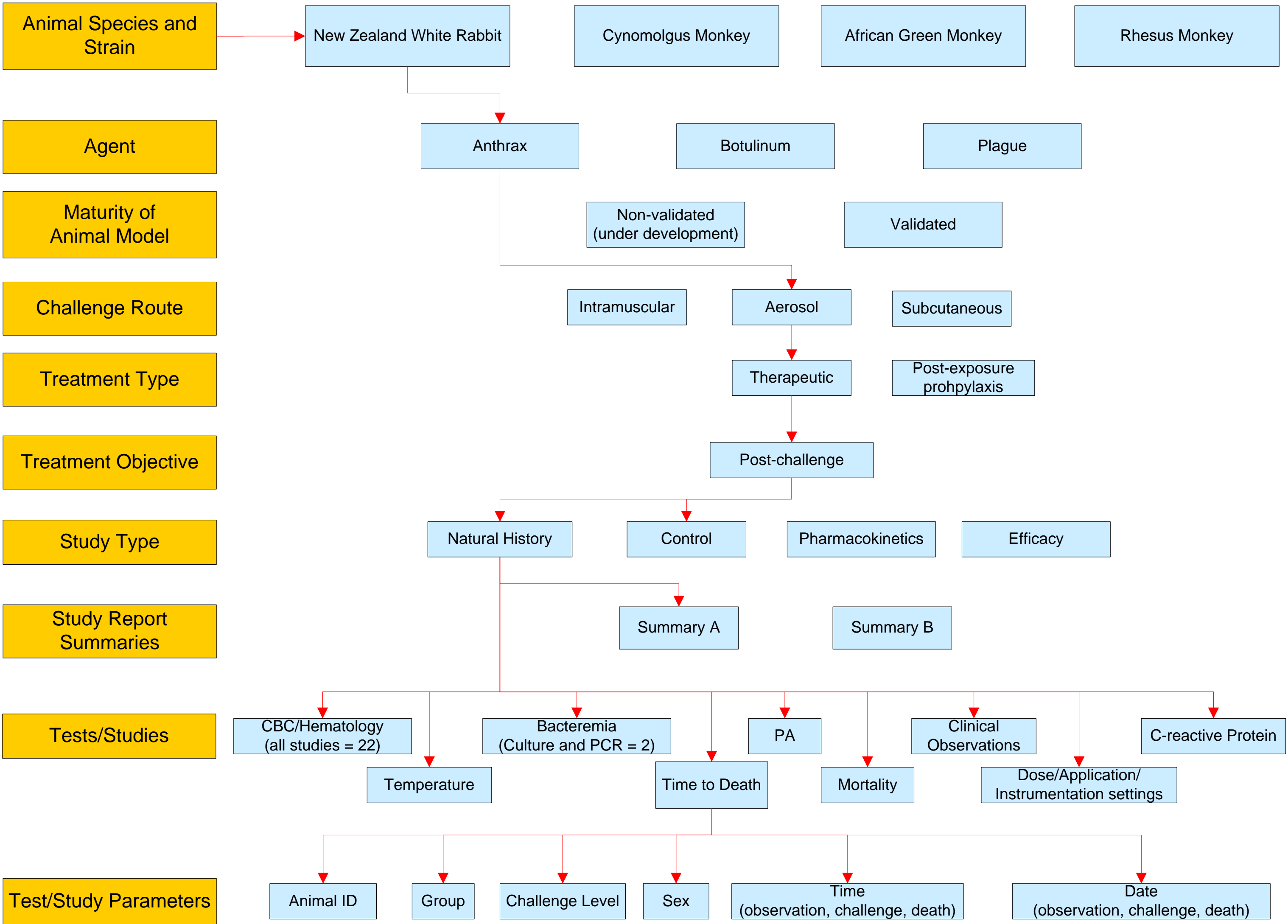

Figure 2. Examples of searchable fields in prototype shared animal model database. Red arrows illustrate a search path.

GOALS

- Establish a central repository of animal model data that can be used by government, industry and academia to accelerate evaluation of therapeutic MCMs.
- Analyze data trends to answer questions relevant to animal model development and product indication (e.g., therapeutic).
- Promote replacement and/or a reduction in the use of animals.
- Identify gaps in existing model development data and identify areas where prospective collaborative data generation could be beneficial.
- Promote standardization.

DEVELOPMENT PROCESS

Participants in the database project include members of Alliance (Biotech, CROs, Center for Biosecurity); and representatives from BARDA, NIAID, USAMRIID, DTRA/TMTI. FDA representatives are observers.

Types of data. The prototype will consist of Animal model information related to Anthrax studies as a first step, since Anthrax is high on the threat priorities list and there exists a critical mass of natural history data available for multiple species.

Data Collection and Templates. To date the Alliance has identified a potential database manager to create a prototype; has collected natural history data on New Zealand White Rabbits; is now collecting non-human primate data; and has created standard templates for submission of:

- Individual test data
- Subject information
- Study reports (summaries)

Searching/Queries. The prototype will allow searching and grouping on a variety of fields (*Figure 2*):

- Aggregation of test results from a number of studies
- Individual tests within a study (body temp, bacteremia, CBC, etc)
- Specific results within tests (temperatures, CBC ranges, etc)
- Information to allow qualitative assessments of studies

The data will be linked to study summary and subject information so that database users have tools to evaluate study data.

Mature database. Once a workable prototype is developed, data will be widely solicited from industry, academia, and government sources. A mature database could:

- Contain efficacy data
- Contain animal model information for other threat agents
- Be regularly updated as data is contributed and be maintained on a quarterly basis

Access. The Alliance seeks to make the database as accessible to as many bona fide researchers as possible, with recognition that an appropriate level of security must be maintained. The Alliance recognizes the need to provide incentives for contributing data and expanding the database.

SUMMARY AND NEXT STEPS

A shared animal model database could
- Identify parallel efforts and save resources
- Advance scientific understanding
- Accelerate development of acceptable animal models and MCMs
- Promote standardization

The Alliance is currently:
- Securing funding for the prototype
- Recruiting other data contributors

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