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### Introduction

The BRisk (Blood Risk) and GREAT (Geographic Risk Evaluation and Assessment Tool) applications were developed to help respond to two challenges that can hinder quick risk assessment and regulatory decision making. The first challenge involves aggregating geographic data that is spread across a variety of sources. The second challenge involves rapidly creating probabilistic models to perform risk assessment of how to respond to an emerging threat, which for BRisk and GREAT, involves evaluating potential interventions to an infectious disease that may impact the blood supply.

# **GREAT and BRisk Expedite Risk Analysis**

First, GREAT addresses the challenge of integrating detailed data about a transfusion transmitted disease into one application and allows users to view this data on a map. From here, users can identify the countries which represent the most risk and perform a quick analysis of the impact of potential interventions, including blood testing and donor deferral for blood donors traveling to those countries.



Figure 1: Evaluating risk in GREAT

Figure 2: Comparing interventions in BRisk

The next step for users is to evaluate the impact of these potential interventions using probabilistic models, and BRisk helps expedite this process. CBER has previously developed probabilistic model templates using Lumina's Analytica, which models diseases with different exposure mechanisms. These models contain hundreds of nodes but only a small handful need to be updated to model a different disease. BRisk assists users by exposing only the nodes that need to be updated and provides a web interface for updating, running and sharing the model results with others. **BRisk** 

and GREAT

Modeling and simulation tools for risk assessment and policy evaluation on AWS to assist CBER in responding to emerging infectious diseases that may impact the safety of U.S. blood supply.

### **Development and Deployment**

- What technologies are used in BRisk and GREAT?
  - The applications use Angular JavaScript, Plot.ly and ArcGIS JavaScript in the user interface and use Analytica Decision Engine, C# and Java in the back end.
  - Amazon Web Services (AWS) resources used include EC2 virtual servers, Aurora relational database service, S3 storage, API gateway and Lambda serverless functions.
- Where were the applications developed?
  - The applications were originally developed on the OIMT Innovation Lab Sandbox, which allows for experimentation with technologies not currently on the Master Approved Technology List.
- Where are the applications hosted now?
  - They are hosted on FDA's GovCloud West AWS organization in the test enclave. You can learn more about AWS at the FDA at <u>FDA Cloud</u> laaS (sharepoint.com).

## Conclusions

Developers are deploying the applications for production use by selected FDA Office of Blood Research and Review users on the FDA GovCloud West Organization. These applications could be used to conduct other types of risk assessment within CBER and at other centers at FDA.

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