BIOMARKERS IN CLINICAL DRUG DEVELOPMENT

Sreeni Devidas, Ramadevi Sanam, Sunita Tajne, Sarma Jagarlapudi

GVK Biosciences, S-1, Phase-1, Technocrats Industrial Estate, Balanagar, Hyderabad – 500037, INDIA
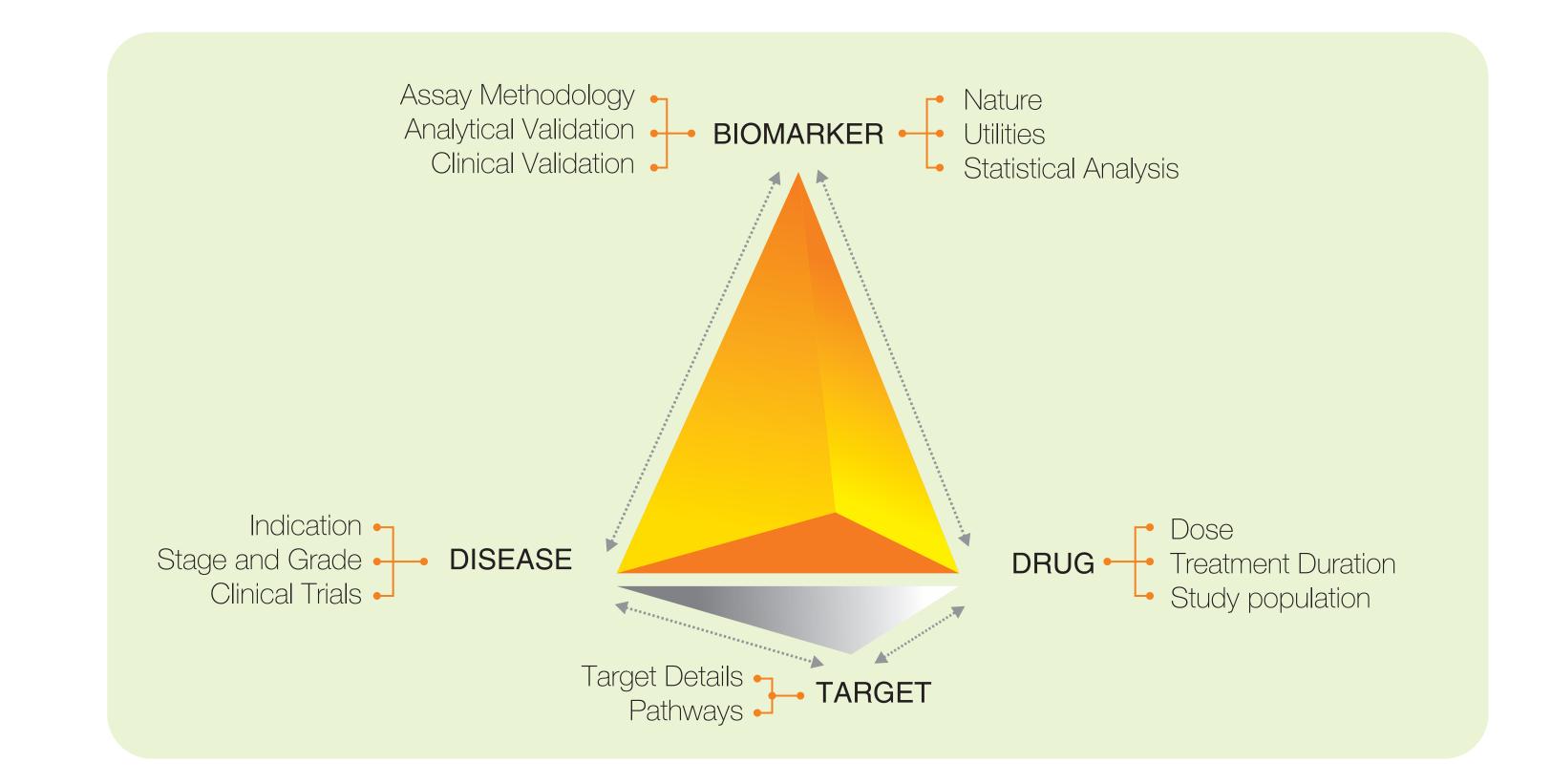
Introduction

- GOBIOM (GVK BIO Online Biomarker Database) is a repository of all clinical and preclinical biomarkers measured for different therapeutic indications.
- Active collaboration with US FDA Genomics Group.
- Member of NIH Biomarker Consortium.
- A Proprietary Tetrahedron Model adopted in the framework of the database linking four critical parameters i.e. Biomarkers, Therapeutic area, Drug and the Target. This unique model simplifies the process of biomarker data analysis.
- Database with a user friendly web-based UI that allows users to query the data in multiple ways.
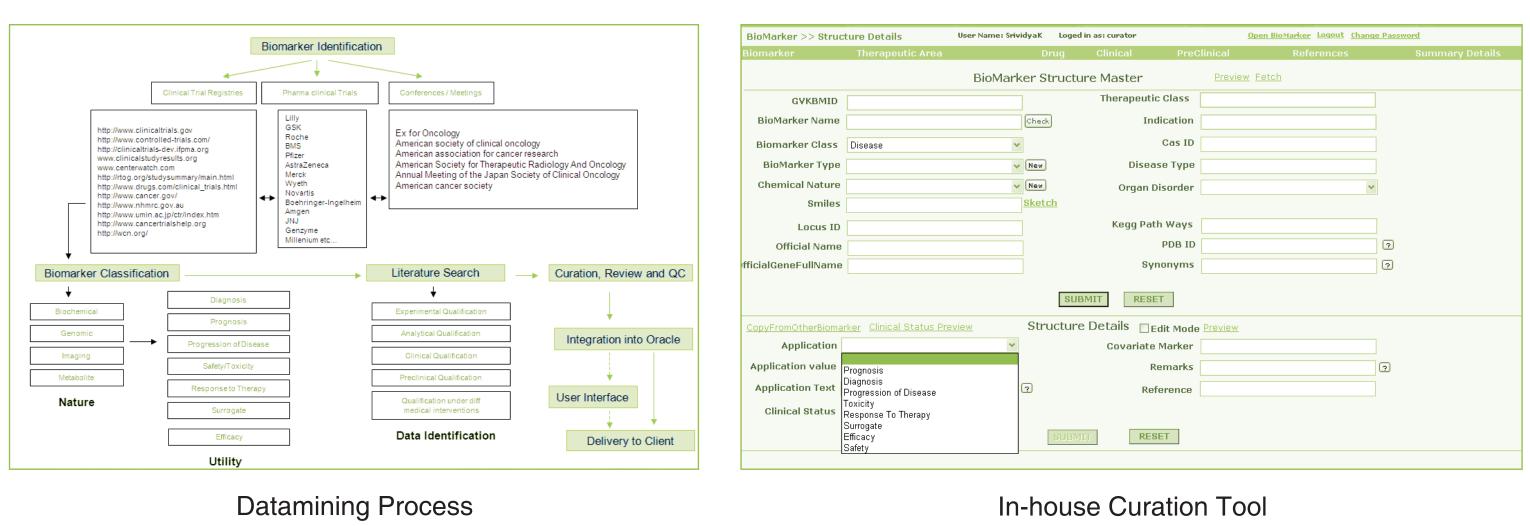

Database Development

Data is manually curated from the following resources:

- Clinical Trial Registries.
- Validated clinical trial results from pharma companies.
- Scientific Conferences.
- Published Literature and other web resources.

60 Scientists entering the data using in-house curation tool with inbuilt Standard vocabulary.

Datamining Process   In-house Curation Tool

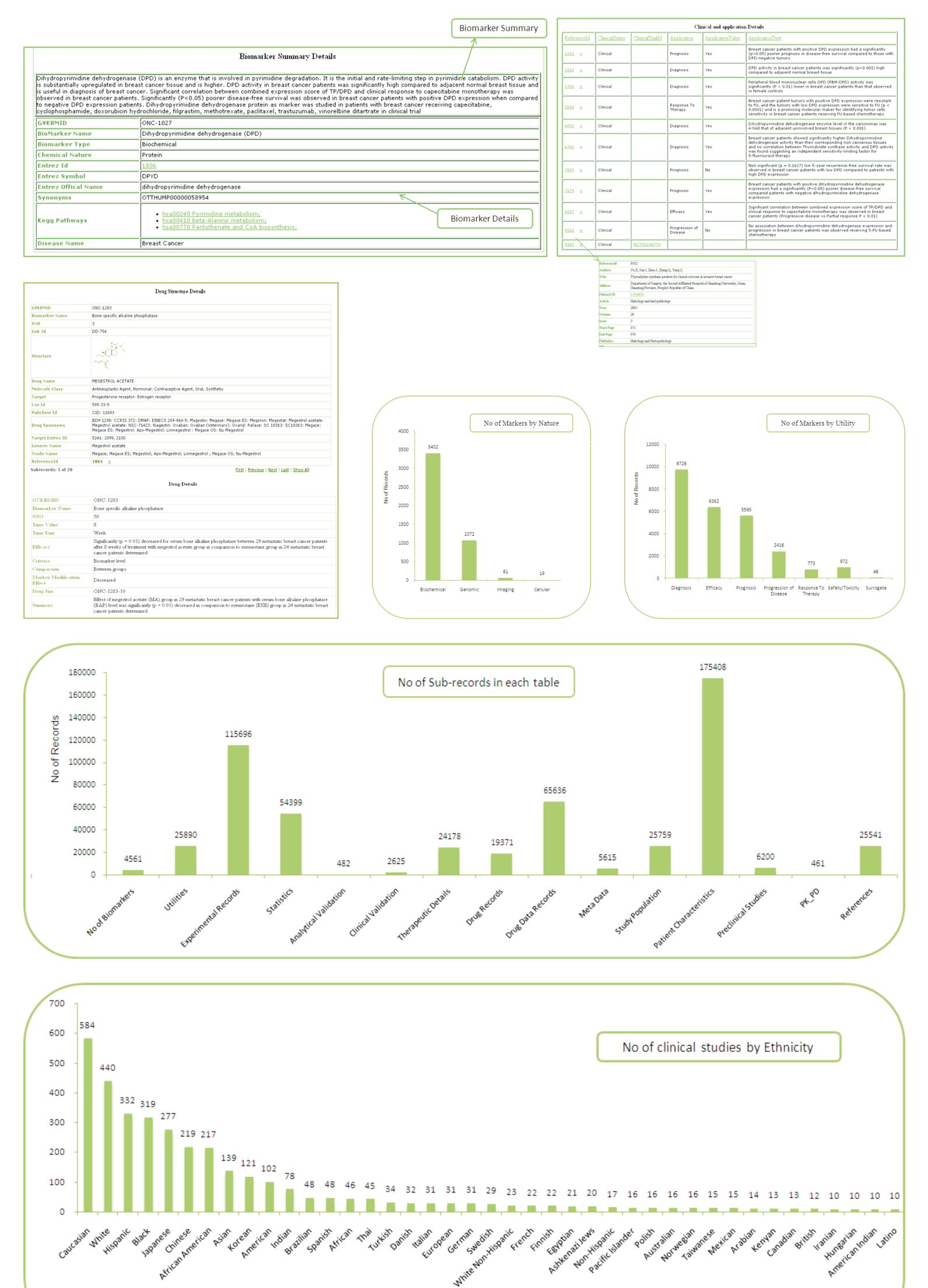
Data Content Till August 2009

Results

Currently, Database has following information for ~4700 biomarkers:

- Details of Clinical Trials in which a Biomarker is measured.
- Multiple utilities of the marker like Diagnosis, Prognosis, Monitoring Disease Progression, Treatment Response, Surrogate, Efficacy and Toxicity / Safety.
- Analytical and Clinical qualification of the Biomarker with Sensitivity, Specificity and Accuracy data published in various journals.
- Statistics focusing the relation between the biomarker and various clinical end points/traits.
- Therapeutic interventions, dose, treatment duration and the relation between the biomarker and clinical outcome along with adverse effects.
- Details on study population with patient background history.
- Preclinical qualification of the marker.

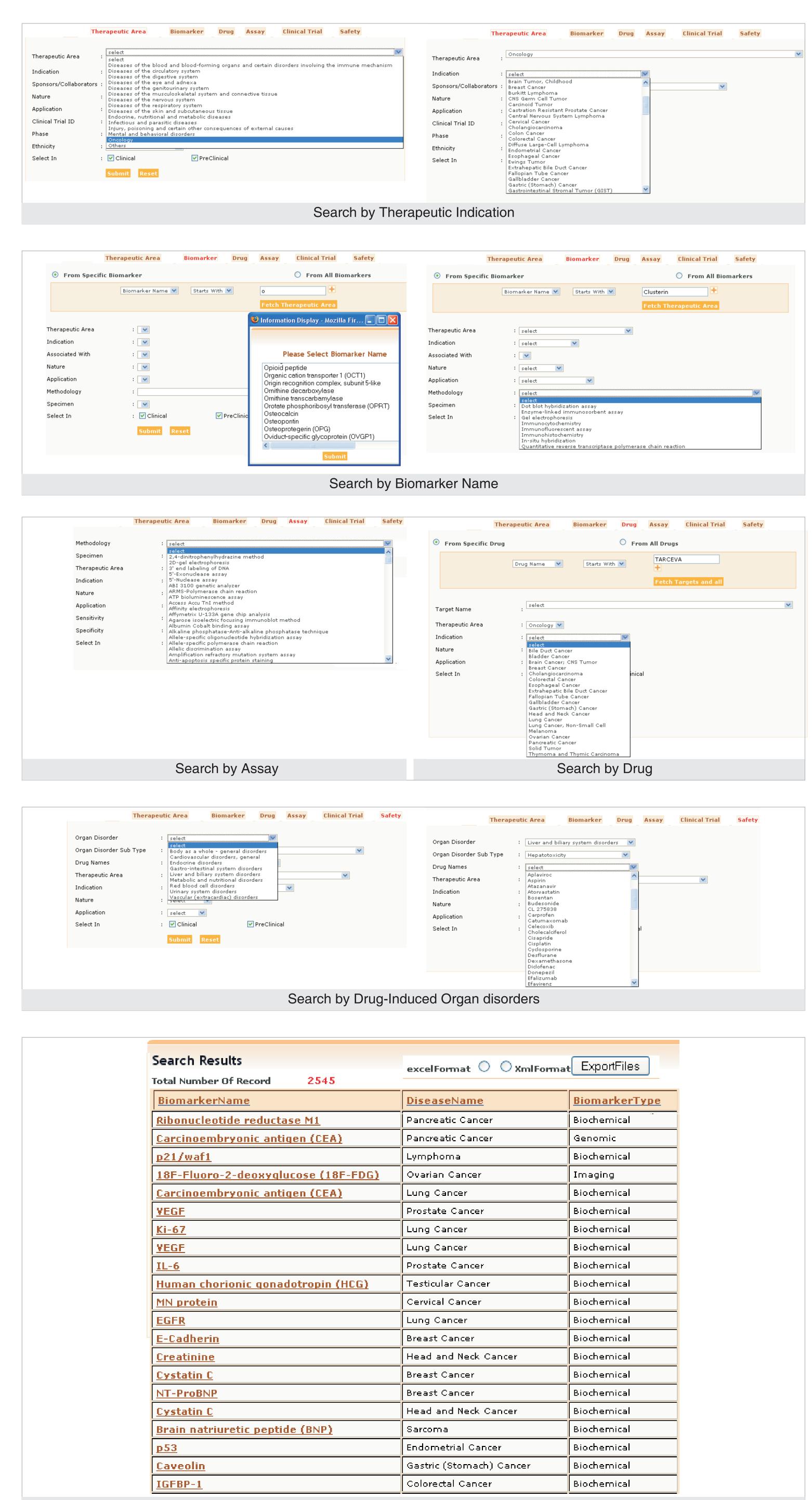All the data points are linked to the valid references.

A user interface is designed for meaningful extraction of data making the query possible from four different angles.

Entire data is stored in a relational database with different export options like Oracle dump, Excel, XML, which a user favor, in analyzing the Biomarker data with respect to its utilities, clinical end points, study population, patient characteristics, medical intervention and the desired outcome.

User Interface

- Web-enabled application with minimal installation requirements.
- A User Interface is designed for meaningful extraction of data making the query possible from either Therapeutic area or Biomarker name or Clinical Trial ID or Assay Methodology or the Organ Toxicities.
- Export options to Excel, XML makes the Biomarker analysis easy.

Search by Therapeutic Indication

Search by Biomarker Name

Search by Assay   Search by Drug

Search by Drug-Induced Organ disorders

Search-Result Export Options

Database Strengths

- Over 350 datafields captured for every biomarker.
- 365 therapeutic indications covered.
- Controlled vocabulary through out the database.
    - Standard WHO Nomenclature for disease classification.
    - MEDRA for Toxicity nomenclature.
    - CTCAE grades for Adverse events.
- 26,258 records on different biomarker utilities with pro and contradictory information.
- 54,750 records on the statistical correlation between the biomarker and clinical end points.
- 117,000 experimental records with ~500 unique assay methodologies.
- 70 Assay methodologies with analytical qualification data for different biomarkers.
- 65,636 drug data records for 1,713 unique drugs. Each drug data record has information on dose, treatment duration, study population details and biomarker outcome.
- Biomarker studies in 167 different ethnic groups.
- ~200 Drug-Induced Toxicity Markers covering Hepato, Neuro, GI, Nephro, Cardio, Endocrinal, Vascular and other Toxicities.
- Manual curation of the data with periodic updation.
- Easy integration with client proprietary data.
- Alert service on new marker addition or existing marker updation.
- On-demand service for any biomarker addition into the database.
- Competitive intelligence analysis.
- On-demand training sessions.

Future Developments

- Addition of preclinical biomarkers from patent and non-patent literature.
- Linkage of statistical tools for easy data analysis.
- Service on Biomarker data analysis.
- Search on all the database fields.

Contact Information

Sreeni Devidas Ph.D
GVK BIO, Inc., 5457 Twin Knolls Rd., Suite 101, Columbia, MD 21045
Tel : (443) 838-6260   Email : sreeni.devidas@gvkbio.com

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