Biomedical Informatics for Clinical Decision Support – a vision for the 21st Century: **Informatics Infrastructure – NIH Perspective**

Ken Buetow

NCICB/NCI/NIH/DHHS

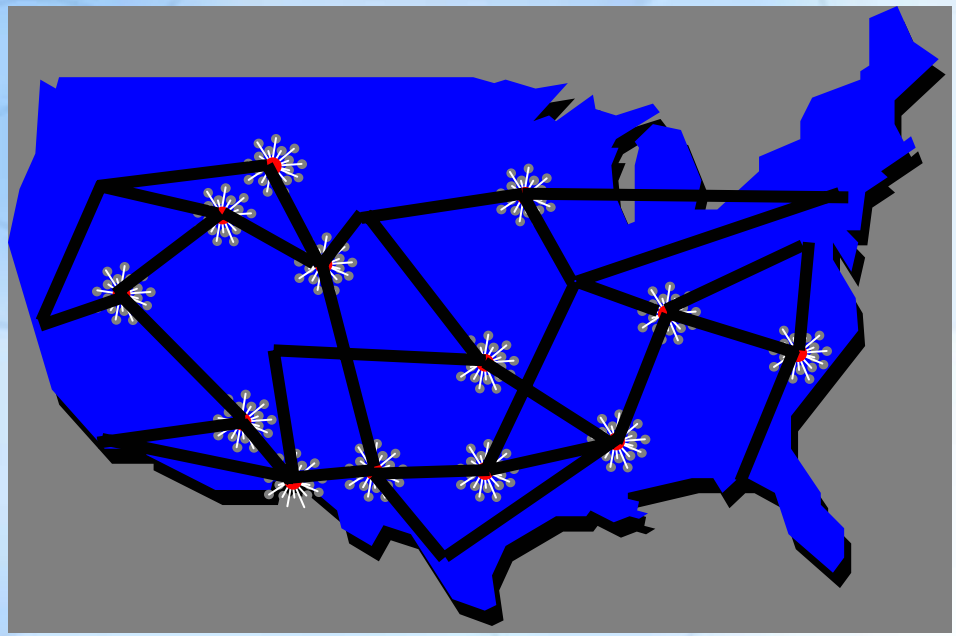
Re-engineering the CR Enterprise

- Integration of CR networks and CR Informatics
  - Pilot NECTAR network
- Facilitate translational research
- Enhanced training
- Clinical Research Corps
- Coordination and Support of CR regulatory policies and processes

Integration of Clinical Research Networks

Establish interoperable networks where clinical studies and trials can be effectively conducted

Ensure that patients, physicians and scientists form true "Communities of Research"



NECTAR Network

- A national network of new and extant CR sites, programs, and systems
  - National Electronic Clinical Trials and Research (NECTAR) Network
- Linking will synergistically:
  - Expand their utility, functionality
  - Maximize connectivity
  - Provide unprecedented analytical capacity

NECTAR: Three Foci

- **Data Standards**
  - Common exchange standards and vocabularies (e.g., HL-7, LOINC, SNOMED)
- **Tools**
  - Software applications to support clinical research tasks (protocol preparation and review; IRB mgmt; AE reporting; data collection, analysis and reporting)
- **Network Infrastructure**
  - Platforms, architectures, integrating elements

Clinical Research Inventory

- **Estimated Start Date: September 30, 2004**
- **Estimated Completion Date: June 30, 2006**
- **Major Goals:**
  - **Develop inventory and database of existing clinical research networks**
  - **Detailed description of existing practices and assessment of best practices**
  - **National Leadership Forum on the results of inventory and the assessment of studies**

Feasibility of Integrating and Expanding Clinical Research Networks

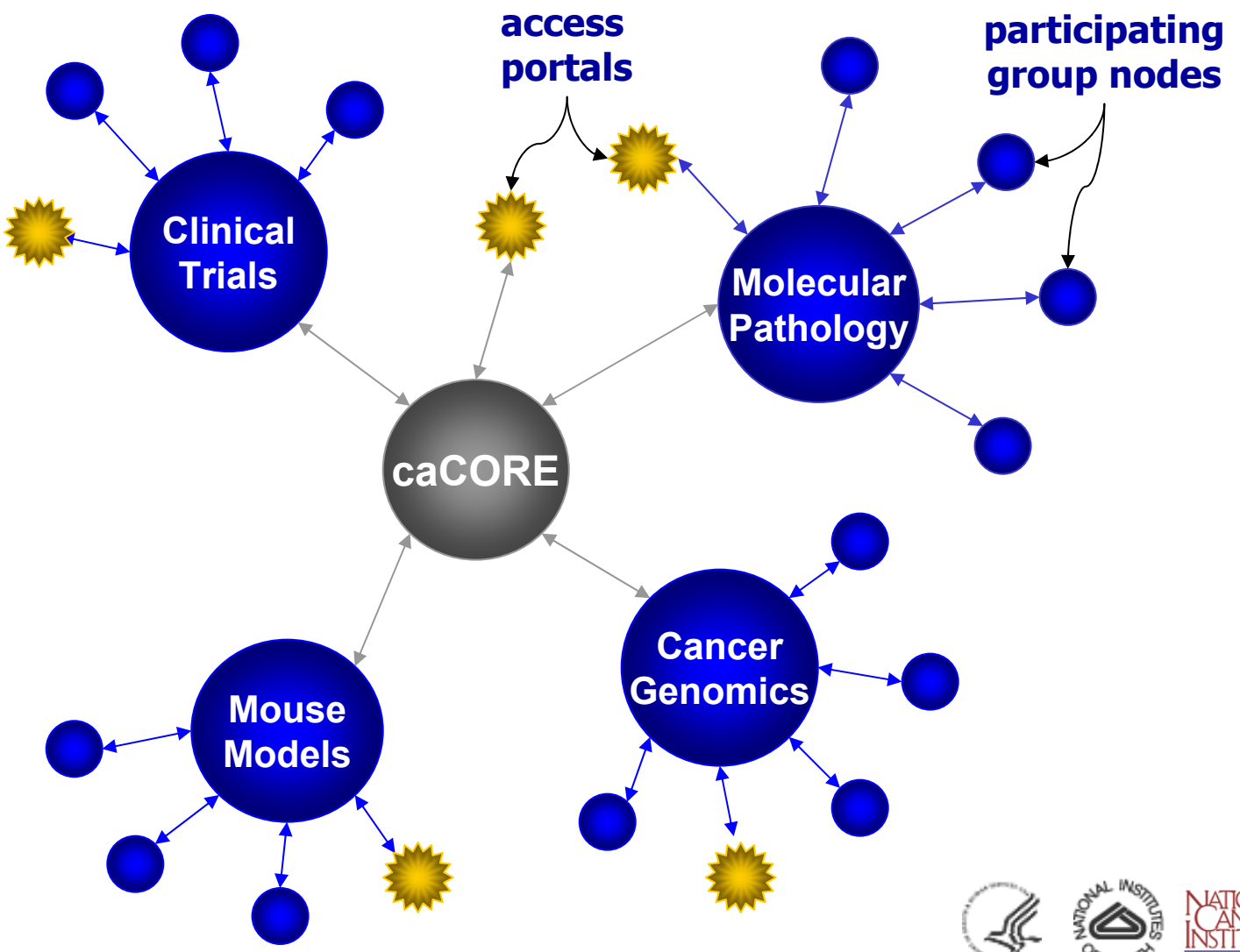
(BAA-RM-04-23)

- Foster clinical research networks that are based on common or inter-operable infrastructure elements and that conduct research both in academic and clinical care settings.
- Integrate and expand clinical research networks will broaden the kinds of research questions that can be addressed and enhance the efficiency of conducting clinical research.
- Solicit feasibility study proposals that will test methods; activities to expand, broaden, and optimize existing approaches and can be generalized to the greater clinical research community.

NCI biomedical informatics

- ***Goal:*** A virtual web of interconnected data, individuals, and organizations redefines how research is conducted, care is provided, and patients/participants interact with the biomedical research enterprise

building common architecture, common tools, and common standards



Courtesy: Charlie Mead

Interoperability

- **in·ter·op·er·a·bil·i·ty**
  - ability of a system...to use the parts or equipment of another system

    Source: Merriam-Webster web site

- **interoperability**
  - ability of two or more systems or components to exchange information and to use the information that has been exchanged.

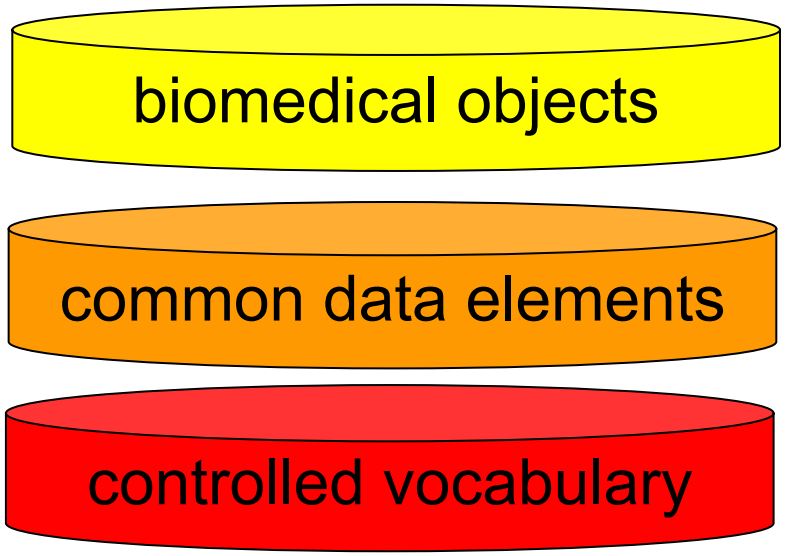
    Source: IEEE Standard Computer Dictionary: A Compilation of IEEE Standard Computer Glossaries, IEEE, 1990]

Syntactic interoperability

Semantic interoperability

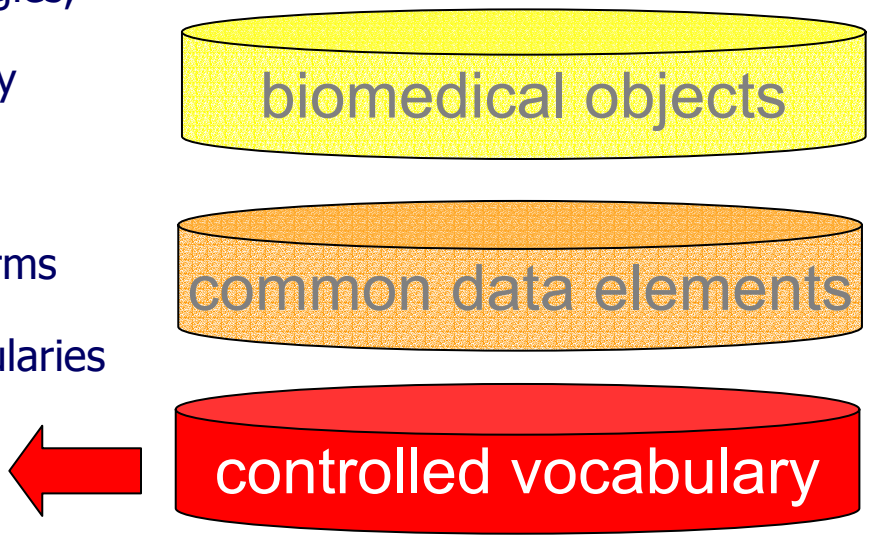
caCORE – common ontologic representation environment

- Information integration
- Cross-discipline reasoning



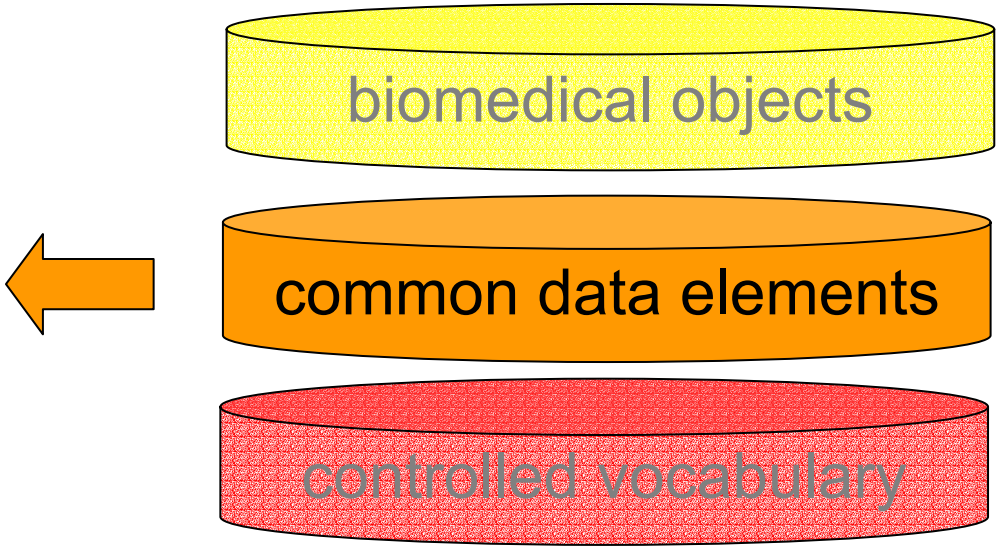
Enterprise Vocabulary

- **NCI Meta-Thesaurus**
  (Cross-map standard vocabularies/ontologies, e.g. SNOMED, MEDRA, ICD)
  - Semantic integration, inter-vocabulary mapping
  - UMLS Metathesaurus extended with cancer-oriented vocabularies
    - 800,000 Concepts, 2,000,000 terms and phrases
    - Mappings among over 50 vocabularies
- **NCI Thesaurus**
  - Description logic-based
  - 18,000 "Concepts"
    - Concept is the semantic unit
    - One or more terms describe a Concept – synonymy
    - Semantic relationships between Concepts



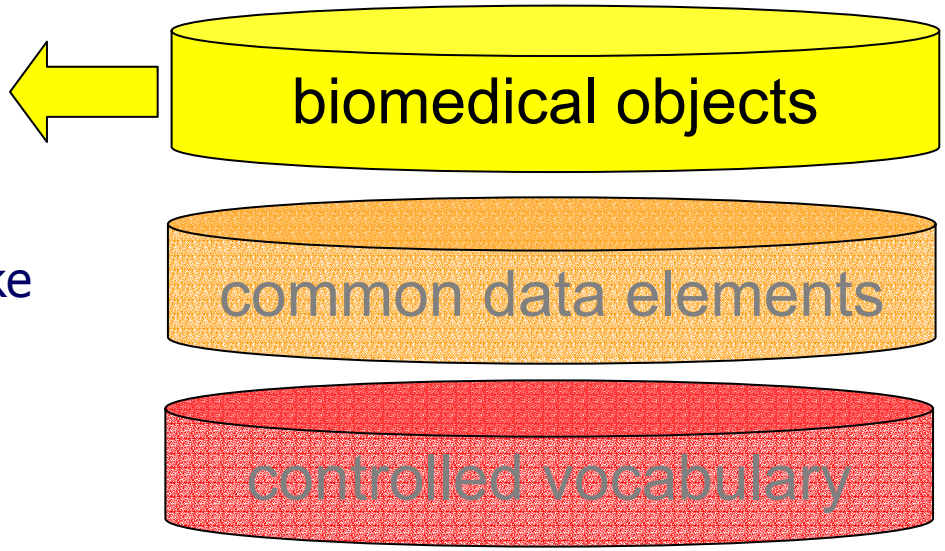
Common Data Elements

- Structured data reporting elements (e.g. LOINC)
- ISO11179 compliant



Biomedical Information Objects

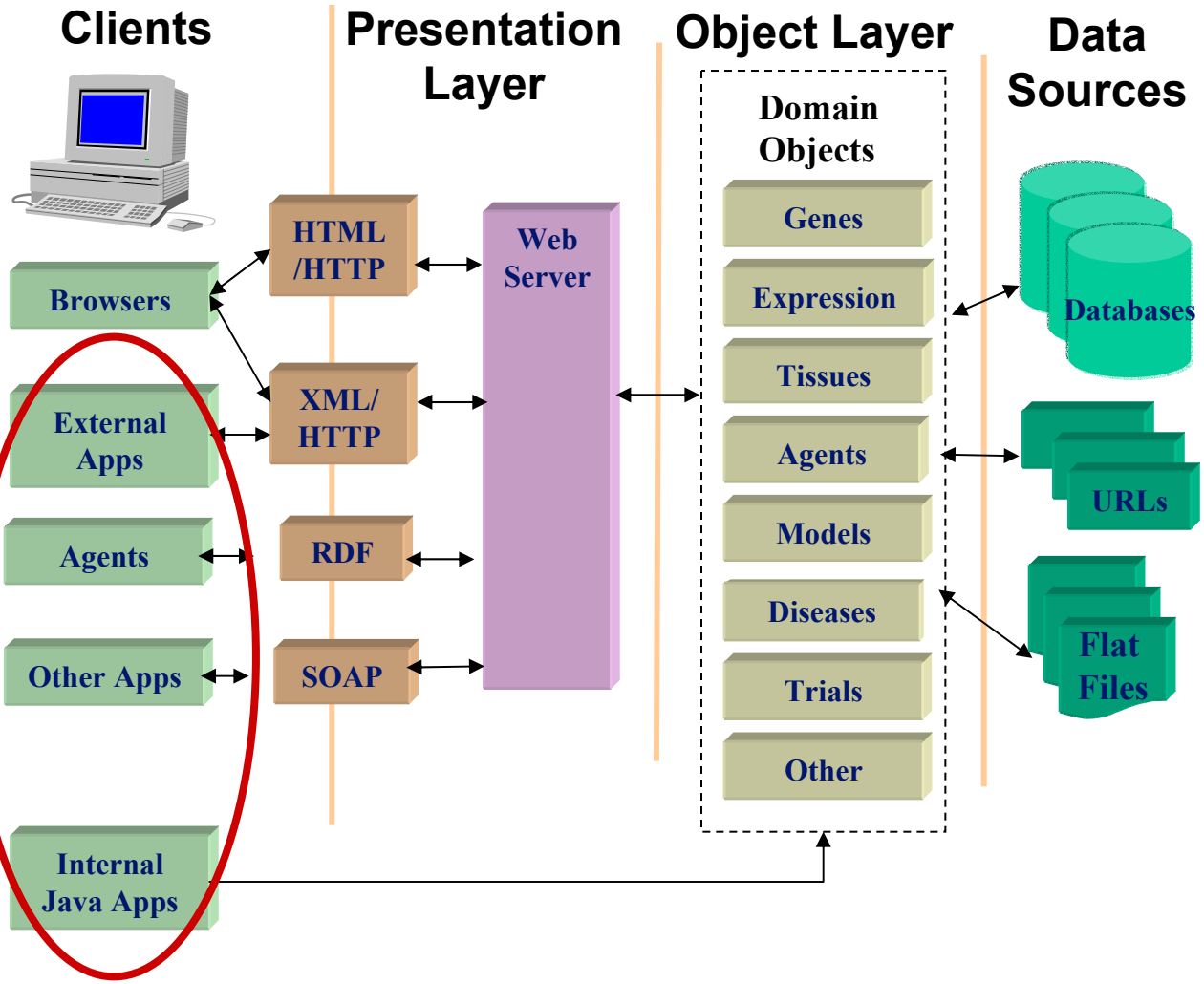
- Computer model of a biomedical object – "Plato's Forms"
  - capture properties of object
  - can be joined together to make complex systems
  - isolate data from data source
  - isolate applications from data
- Examples:
  - HL7-RIM
  - MAGE-OM



Standards Supporting Infrastructure

- Enterprise Vocabulary Services (EVS)
- cancer Data Standards Repository (caDSR)
- cancer Bioinformatics Infrastructure Objects (caBIO)

...an open, sharing architecture



- open source
- open development
- open access
- federated

Cancer Biomedical Informatics Grid (caBIG)

- Common, widely distributed infrastructure permits cancer research community to focus on innovation
- Shared vocabulary, data elements, data models facilitate information exchange
- Collection of interoperable applications developed to common standard
- Raw published cancer research data is available for mining and integration

caBIG action plan

- Establish pilot network of Cancer Centers
  - Groups agreeing to caBIG principles
  - Mixture of capabilities
  - Mixture of contributions
- Expanding collection of participants
- Establish consortium development process
  - Collecting and sharing expertise
  - Identifying and prioritizing community needs
  - Expanding development efforts
- Moving at the speed of the internet…

caBIG cancer Biomedical Informatics Grid

Three Domain Workspaces and two Cross Cutting Workspaces will be launched during the Pilot phase

DOMAIN WORKSPACE 1
Clinical Trial Management Systems

Will address the need for consistent, open and comprehensive tools for clinical trials management.

DOMAIN WORKSPACE 2
Integrative Cancer Research

Will provide tools and systems to enable integration and sharing of information.

DOMAIN WORKSPACE 3
Tissue Banks & Pathology Tools

Will provide for the integration, development, and implementation of tissue and pathology tools.

Will be responsible for evaluating, developing, and integrating systems for vocabulary and ontology content, standards, and software systems for content delivery

CROSS CUTTING WORKSPACE 1
Vocabularies & Common Data Elements

Will develop architectural standards and provide architectural assistance as necessary to other workspaces.

CROSS CUTTING WORKSPACE 2
Architecture

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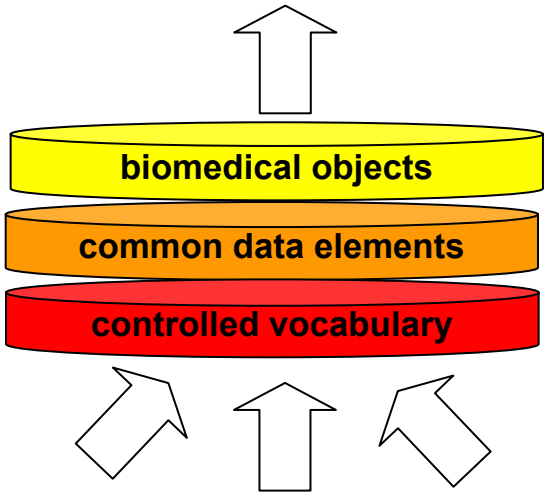
caBIG deliverables

- Componentized, standards-based Clinical Trials Management System
  - e-IND filing/regulatory reporting with FDA
  - Electronic management of trials
  - Integration of diverse trials
- Tissue Management System
  - Systematic description and characterization of tissue resources
  - Ability to link tissue resources to clinical and molecular correlative descriptions
- "Plug and Play" analytic tool set
- Diverse library of raw, structured data

Cancer Molecular Analysis Project (CMAP)
- a prototypic biomedical data integration effort

Profiles, Targets, Agents, Clinical Trials



NCBI

UCSC (via DAS)

CGAP

Gene Ontologies

KEGG

BioCarta

CGAP gene expression

CTEP clinical trials

NCI drug screening

NCI drug screening

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Cancer Molecular Analysis Project

Molecular Profiles | Molecular Targets | Molecular Targeted Agents | Trials

Current Context

Tissue:
All Tissues

Histology Type:
All Types

Histology Subtype:
All Subtypes

Change Context

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- NCICB Home

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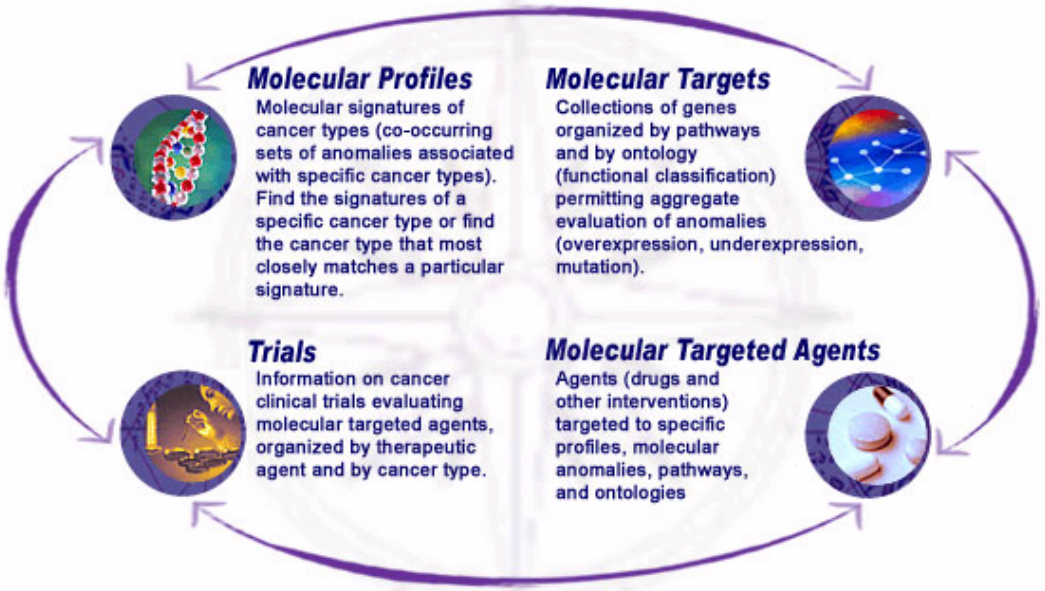
The Cancer Molecular Analysis Project



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SAGE Expression Data:
Highest Mean Across Columns 36-43

Help

Lowest Highest
Missing Value

Column Index

36: SAGE_SciencePark_MCF7_estradiol_3h [breast cancer]
37: SAGE_SciencePark_MCF7_estradiol_10h [breast cancer]
38: SAGE_SciencePark_MCF7_Control_0h [breast cancer]
39: SAGE_DCIS [breast cancer]
40: SAGE_95-348 [breast cancer]

Pivot On Column 1

Hide index

Gene	Acc.	Mean
Hs.322802...	ATTCTCCAGT	1470.5312
RPL27A	GAGGGAGTTT	1373.2900
RPL41	TTGGTCCTCT	1303.4237
RPS19...	CTGGGTTAAT	1302.2037
RPL32	TGCACGTTTT	1195.6875
RPS29	ATAATTCTTT	1103.3125
Hs.187527...	ACTTTTTCAA	1087.9462
FTH1	TTGGGGTTTC	1077.1300
KRT8	CCTCCAGCTA	1036.3150
RPL30	CCAGAACAGA	1018.8125
FLJ20030...	TAGGTTGTCT	957.0175
	AGGCTACGGA	844.8500
	GCATAATAGG	808.7587
RPL29...	GGGCTGGGGT	807.7725
RPS27	CACAAACGGT	784.6925
Hs.233125...	TTCAATAAAA	780.0738
COX6C	AATATGTGGG	779.9713
	AGGGCTTCCA	697.7850
	GGACCACTGA	697.3438
EEF2	AGCACCTCCA	662.1225
ATP5A1...	GTGAAGGCAG	633.0662
Hs.314941	CCCATCGTCC	622.5700
RPS4X	TCAGATCTTT	620.9088
SOX21	GGCAAGCCCC	609.1100
H19...	GAAAAATGGT	594.3500
GAPD	TACCATCAAT	591.7563
XBP1	CAATTAAAAG	586.6237
RPLP2...	GGATTTGGCC	577.3550
PPIA...	CCTAGCTGGA	549.7100
RPL37A	AAGACAGTGG	523.6463
RPL37...	CAATAAATGT	505.3788
RPL13	CCCGTCCGGA	497.1450
Hs.350733...	GTGAAACCCC	495.0188
B2M	GTTGTGGTTA	489.8575
MYL6	GTGCTGAATG	488.7262
G1P3	CGCCGACGAT	483.8737
CFL1	GAAGCAGGAC	480.1587
RPS25	AATAGGTCCA	462.9962
RPL12	ACATCATCGA	457.3288

Done Internet

Column Index

41: SAGE_95-259 [breast cancer]
42: SAGE_95-260 [breast cancer]
43: SAGE_95-347 [breast cancer]
44: SAGE_mammary_epithelium [breast normal]
45: SAGE_Br_N [breast normal]

Pivot On Column 1

Hide index

Gene	Acc.	R	P<
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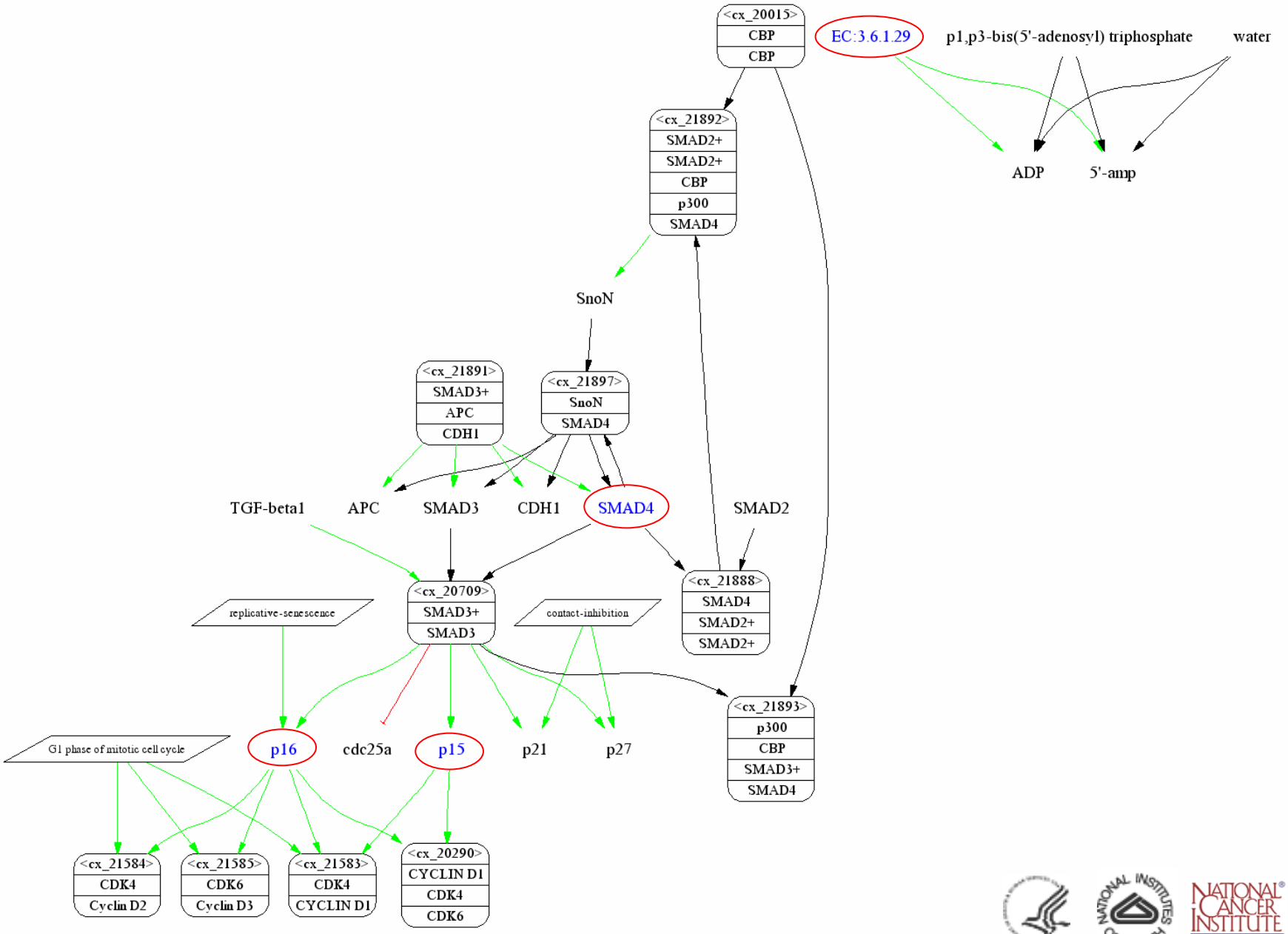
		Positive Correlations	
PSMB3	GGAGTCATTG	0.91	0.00e+00
	CAATGCTGCC	0.88	0.00e+00
	GAGGGCCGGT	0.87	0.00e+00
ERBB2	AGGAAGGAAC	0.86	0.00e+00
	GTGATGGCCA	0.85	0.00e+00
Hs.306962...	TTTTGAAATA	0.84	0.00e+00
	GACCACACCG	0.83	0.00e+00
	CAGCTTAATT	0.83	0.00e+00
MLN51	TGTGGTGGTG	0.82	0.00e+00
HN1	CTTGTGAACT	0.81	0.00e+00
		Negative Correlations	
Hs.272837	GCGAAAACCC	-0.33	4.05e-02
GPS2	CACCCCCAGG	-0.32	1.57e-02
	GTGGTGCGCA	-0.31	2.42e-02
R32184_3	GCCCCGCCCT	-0.31	1.53e-02
	GGCTCCTCGA	-0.31	2.03e-02
SPINT1	GGTGAAGAGG	-0.31	5.14e-02
Hs.334355...	GTGGCAGGCA	-0.30	1.12e-02
Hs.325909...	GTGGCGGGCA	-0.30	1.19e-02
SRP46	GAGCGGGATC	-0.30	1.67e-02
Hs.258500...	CTGAGGCCTG	-0.30	5.50e-02

Panel 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60 61 62 63 64 65 66 67 68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CBP
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SMAD4
SnoN
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contact-inhibition
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CBP
SMAD3+
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cdc25a
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CDK4
CYCLIN D1
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CYCLIN D1
CDK4
CDK6

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CMAP

Cancer Molecular Analysis Project

Molecular Profiles | Molecular Targets | Molecular Targeted Agents | Trials

Current Context

Tissue:
mammary_gland

Histology Type:
All Types

Histology Subtype:
All Subtypes

Change Context

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Quick Links:

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Pathway information provided by BioCarta
(See Terms and Conditions of use)
For information on sources of Pathway diagrams, see Biocarta Pathways HowTo

Current Context: mammary_gland; all; all Switch to a Wider Context

A

- Acetylation and Deacetylation of RelA in Nucleus
- Actions of Nitric Oxide in the Heart
- Activation of cAMP-dependent Protein Kinase, PKA
- Activation of CSK Inhibits Signaling through the T Cell Receptor
- Activation of PKC through G-Protein Coupled Receptors
- Acute Myocardial Infarction
- Adhesion and Diapedesis of Granulocytes
- Adhesion and Diapedesis of Lymphocytes
- Adhesion Molecules on Lymphocyte
- ADP-Ribosylation Factor
- Agrin in Postsynaptic Differentiation
- AhR Signal Transduction Pathway
- AKAP95 Role in Mitosis and Chromosome Dynamics
- AKT Signaling Pathway
- ALK in Cardiac Myocytes
- Alternative Complement Pathway
- Angiotensin II Mediated Activation of JNK Pathway via Pyk2 Dependent Signaling
- Angiotensin-converting Enzyme 2 Regulates Heart Function
- Anthrax Toxin Mechanism of Action
- Antigen Dependent B Cell Activation
- Antigen Processing and Presentation
- Antisense Pathway
- Apoptotic DNA Fragmentation and Tissue Homeostasis
- Apoptotic Signaling in Response to DNA Damage
- Aspirin Blocks Signaling Pathway Involved in Platelet Activation
- ATM Signaling Pathway
- Attenuation of GPCR Signaling

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mammary_gland

Histology Type:
All Types

Histology Subtype:
All Subtypes

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Role of ERBB2 in Signal Transduction and Oncology

Pathway information provided by BioCarta

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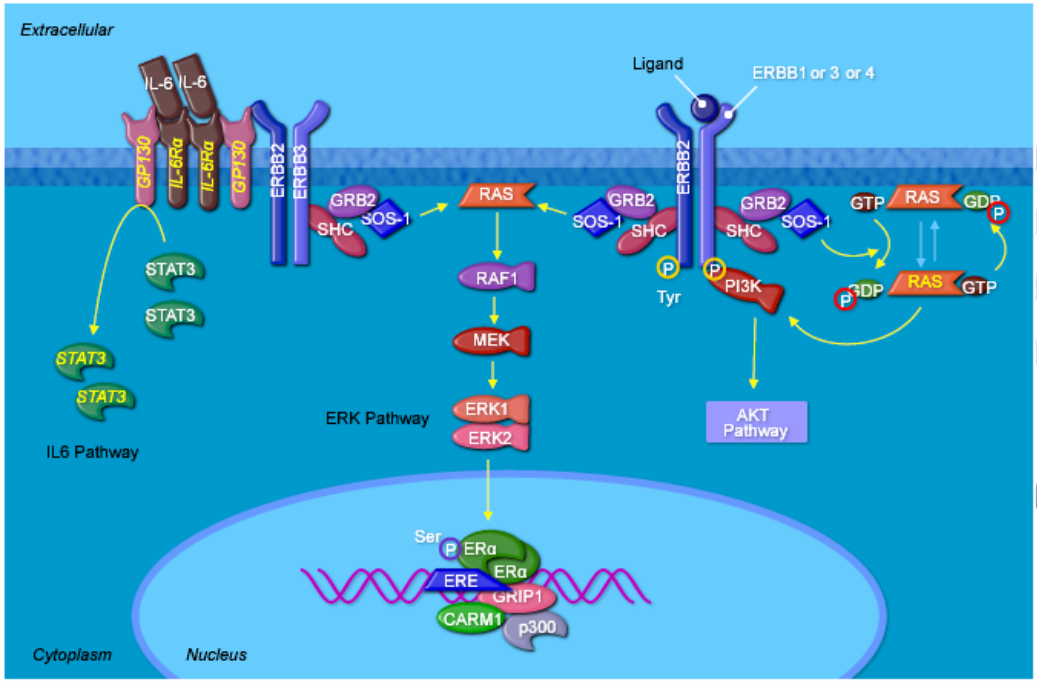
Legend



All Anomolies

Mutated

Expression +/-

Reset

Pathway Summary Report

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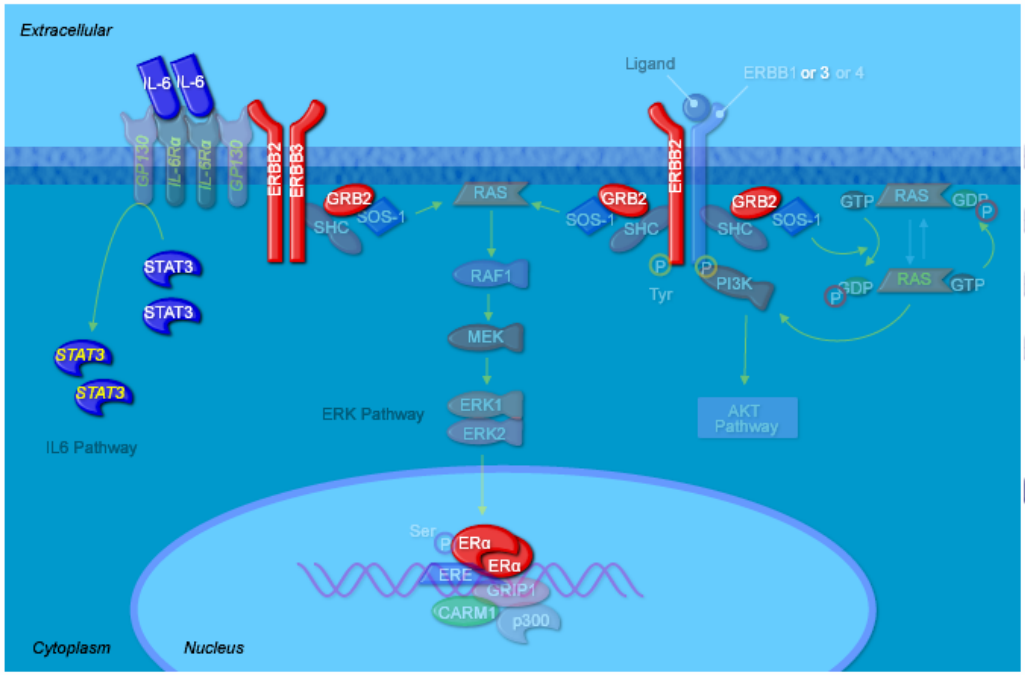

All Anomolies

Mutated

Expression +/-

Reset

Pathway Summary Report

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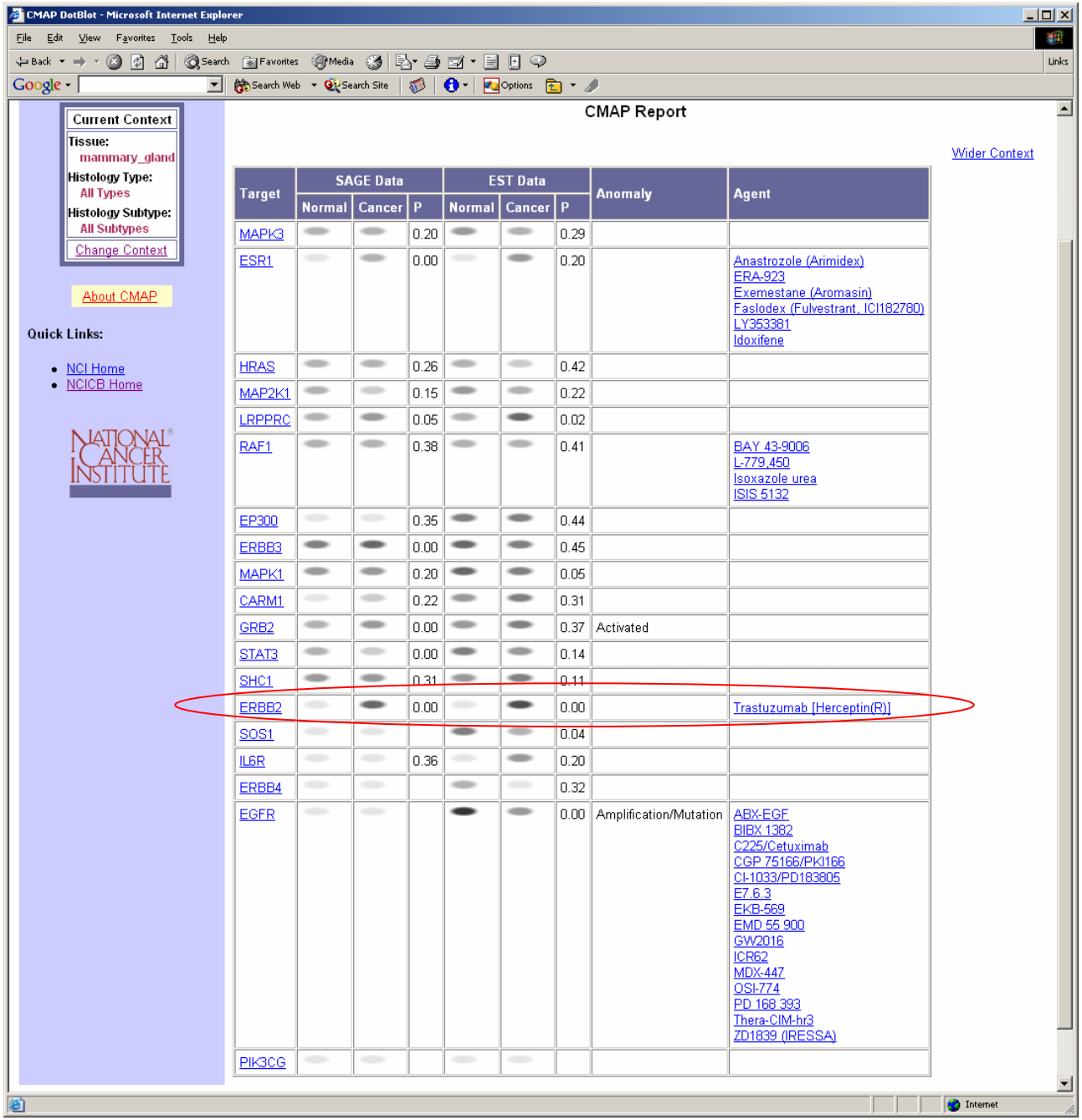
Internet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Tissue:
mammary_gland
Histology Type:
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Histology Subtype:
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Wider Context
Target
SAGE Data
Normal
Cancer
P
EST Data
Normal
Cancer
P
Anomaly
Agent
MAPK3 0.20 0.29
ESR1 0.00 0.20 Anastrozole (Arimidex) ERA-923 Exemestane (Aromasin) Faslodex (Fulvestrant, ICI182780) LY353381 Idoxifene
HRAS 0.26 0.42
MAP2K1 0.15 0.22
LRPPRC 0.05 0.02
RAF1 0.38 0.41 BAY 43-9006 L-779,450 Isoxazole urea ISIS 5132
EP300 0.35 0.44
ERBB3 0.00 0.45
MAPK1 0.20 0.05
CARM1 0.22 0.31
GRB2 0.00 0.37 Activated
STAT3 0.00 0.14
SHC1 0.31 0.11
ERBB2 0.00 0.00 Trastuzumab [Herceptin(R)]
SOS1 0.04
IL6R 0.36 0.20
ERBB4 0.32
EGFR 0.00 Amplification/Mutation ABX-EGF BIBX 1382 C225/Cetuximab CGP 75166/PKI166 CI-1033/PD183805 E7.6.3 EKB-569 EMD 55 900 GW2016 ICR62 MDX-447 OSI-774 PD 168 393 Thera-CIM-hr3 ZD1839 (IRESSA)
PIK3CG
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Current Context

Tissue: mammary_gland
Histology Type: All Types
Histology Subtype: All Subtypes

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Expression Pattern for cluster **Hs.446352**

Text Legend

Tissue	EST Data		SAGE Data		EST Data			SAGE Data		
	Normal	Cancer	Normal	Cancer	Normal	Cancer	P	Normal	Cancer	P
ALL TISSUES					126 / 2076088	230 / 2025142	0.00	85 / 3799195	705 / 8471612	0.00
adipose			--	--	1 / 10228	0 / 767	0.48	--	--	--
adrenal cortex	--		--	--	--	0 / 6427	--	--	--	--
adrenal medulla	--		--	--	--	0 / 321	--	--	--	--
bone			--	--	0 / 13882	2 / 43514	0.36	--	--	--
bone marrow					0 / 15343	1 / 21661	0.38	0 / 204563	0 /	--
brain					2 / 216857	6 / 155717	0.09	4 / 658515	97 / 3814713	0.00
cartilage			--		0 / 4526	4 / 34253	0.37	--	17 / 676933	--
cerebellum					0 / 4413	0 / 0	--	1 / 90885	2 / 252749	0.46
cerebrum		--	--	--	4 / 67147	--	--	--	--	--
cervix			--	--	0 / 1029	1 / 40518	0.49	--	--	--
colon					7 / 17813	60 / 149060	0.45	5 / 98089	8 / 635770	0.05
ear		--	--	--	0 / 12587	--	--	--	--	--
embryonic tissue		--	--	--	0 / 711	--	--	--	--	--
endocrine			--	--	0 / 7403	0 / 3054	--	--	--	--
esophagus			--	--	0 / 84	0 / 2665	--	--	--	--
eye			--	--	12 / 69445	0 / 44426	0.01	--	--	--
gastrointestinal tract			--	--	0 / 664	5 / 12612	0.42	--	--	--
genitourinary			--	--	0 / 1371	5 / 29155	0.43	--	--	--
germ cell	--		--	--	--	2 / 49078	--	--	--	--
head and neck			--	--	1 / 44279	11 / 59793	0.02	--	--	--
heart		--		--	3 / 54913	--	--	0 / 83063	--	--
kidney					0 / 61078	4 / 73670	0.13	4 / 106467	0 /	--
limb	--	--	--	--	--	--	--	--	--	--
liver					1 / 59298	4 / 72824	0.23	1 / 144205	0 /	--
lung					11 / 101837	3 / 165354	0.01	3 / 159917	5 / 122803	0.22
lymph node				--	3 / 81735	0 / 47408	0.24	1 / 99426	--	--
lymphoreticular			--	--	0 / 31611	1 / 77136	0.42	--	--	--
mammary gland					0 / 40987	51 / 82938	0.00	5 / 538122	496 / 1662198	0.00
muscle				--	11 / 71277	3 / 36706	0.20	0 / 107836	--	--
nervous			--	--	5 / 10465	1 / 57863	0.01	--	--	--

Done Internet

Gene Viewer.cgi - displays SNPs in mRNA sequences - Microsoft Internet Explorer

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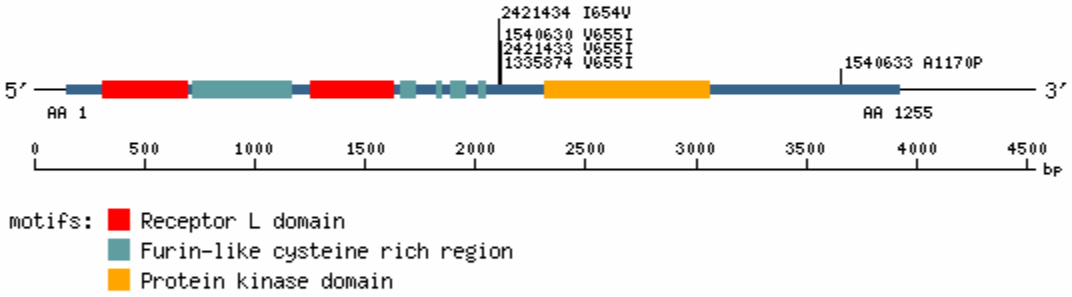
To view protein sequence alignments, statistics about how SNPs affect the fit of protein domains to motif models, and three-dimensional structures of motifs (if known), click here.

mRNA: NM_004448.1
UniGene: Hs.446352 (build 166) [CGAP Gene Info] [CGAP SNP Summary]
Description: v-erb-b2 erythroblastic leukemia viral oncogene homolog 2, neuro/glioblastoma derived oncogene homolog (avian)
Gene symbol: ERBB2
LocusLink ID: 2064



SNP ID	CGAP SNP?	Nucleotide	cds SNP?	Status	Primer Set
ss2421434	no	2110	Ile654Val	-	-
ss1335874	no	2113	Val655Ile	-	-
ss1540630	no	2113	Val655Ile	-	-
ss2421433	no	2113	Val655Ile	-	-
ss1540633	no	3658	Ala1170Pro	-	-

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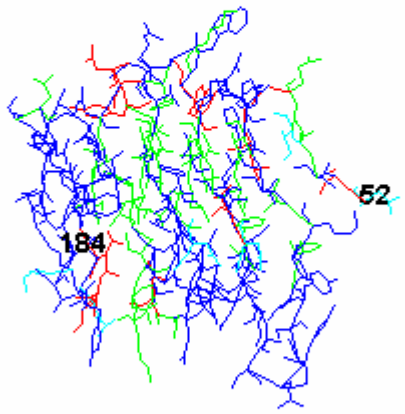
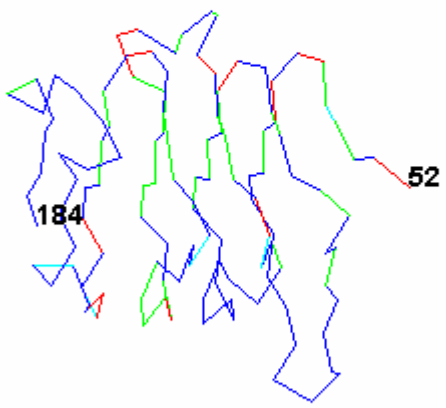
pdb1igr Chain A - Microsoft Internet Explorer

NM_004448.1		LPG id: R7972		
Domain #1				
PF01030	IG1R_HUMAN	52	to	184
pdb1igr	Chain: A	51	to	171

Molecule-View

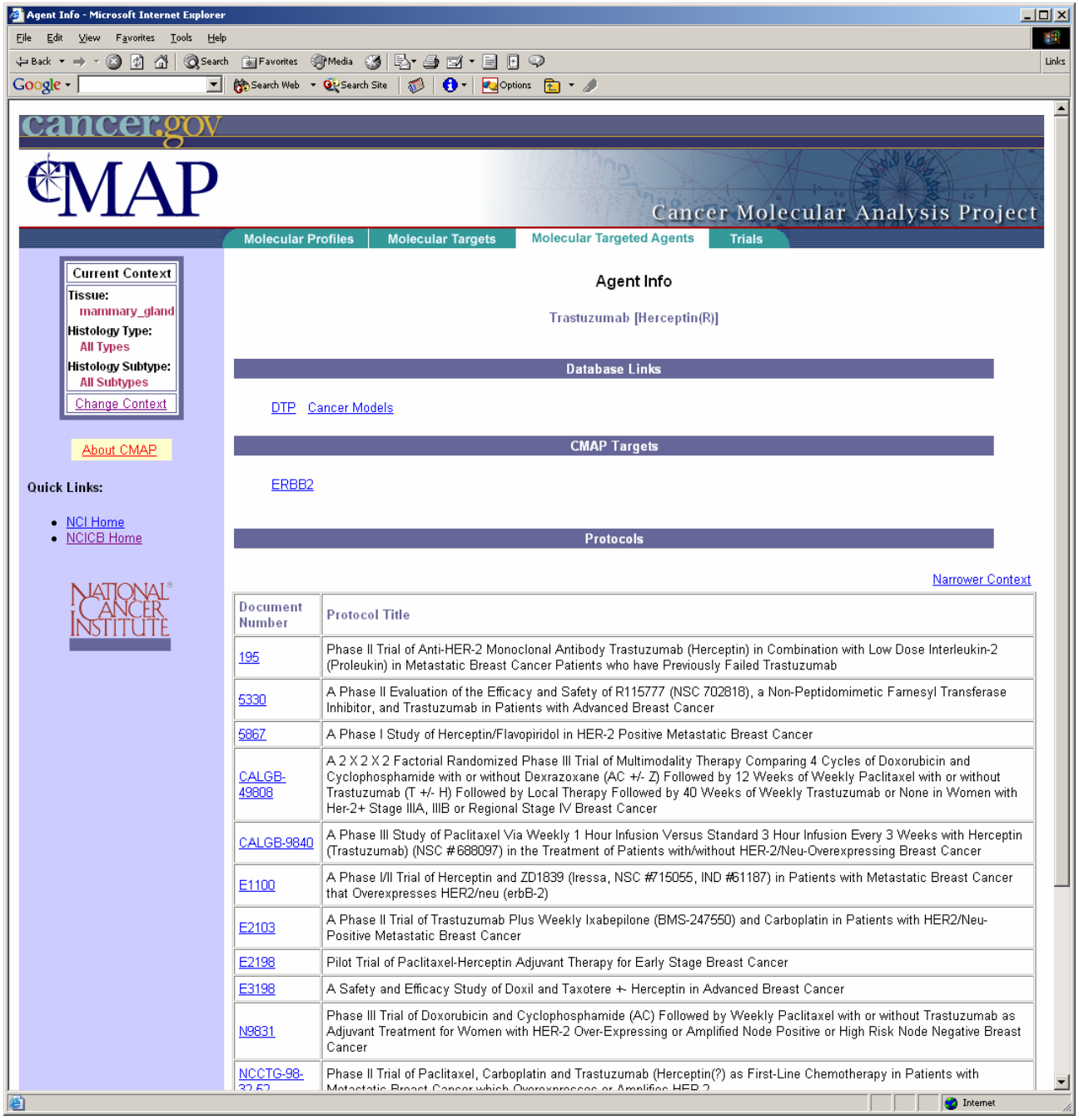


Backbone-View



Drag mouse to rotate;

Drag mouse while holding the Shift key to zoom in or out.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CMAP
Cancer Molecular Analysis Project
Molecular Profiles
Molecular Targets
Molecular Targeted Agents
Trials
Current Context
Tissue:
mammary_gland
Histology Type:
All Types
Histology Subtype:
All Subtypes
Change Context
About CMAP
Quick Links:
NCI Home
NCICB Home
NATIONAL CANCER INSTITUTE
Agent Info
Trastuzumab [Herceptin(R)]
Database Links
DTP Cancer Models
CMAP Targets
ERBB2
Protocols
Narrower Context
Document Number
Protocol Title
195
Phase II Trial of Anti-HER-2 Monoclonal Antibody Trastuzumab (Herceptin) in Combination with Low Dose Interleukin-2 (Proleukin) in Metastatic Breast Cancer Patients who have Previously Failed Trastuzumab
5330
A Phase II Evaluation of the Efficacy and Safety of R115777 (NSC 702818), a Non-Peptidomimetic Farnesyl Transferase Inhibitor, and Trastuzumab in Patients with Advanced Breast Cancer
5867
A Phase I Study of Herceptin/Flavopiridol in HER-2 Positive Metastatic Breast Cancer
CALGB-49808
A 2 X 2 X 2 Factorial Randomized Phase III Trial of Multimodality Therapy Comparing 4 Cycles of Doxorubicin and Cyclophosphamide with or without Dexrazoxane (AC +/- Z) Followed by 12 Weeks of Weekly Paclitaxel with or without Trastuzumab (T +/- H) Followed by Local Therapy Followed by 40 Weeks of Weekly Trastuzumab or None in Women with Her-2+ Stage IIIA, IIIB or Regional Stage IV Breast Cancer
CALGB-9840
A Phase III Study of Paclitaxel Via Weekly 1 Hour Infusion Versus Standard 3 Hour Infusion Every 3 Weeks with Herceptin (Trastuzumab) (NSC #688097) in the Treatment of Patients with/without HER-2/Neu-Overexpressing Breast Cancer
E1100
A Phase I/II Trial of Herceptin and ZD1839 (Iressa, NSC #715055, IND #61187) in Patients with Metastatic Breast Cancer that Overexpresses HER2/neu (erbB-2)
E2103
A Phase II Trial of Trastuzumab Plus Weekly Ixabepilone (BMS-247550) and Carboplatin in Patients with HER2/Neu-Positive Metastatic Breast Cancer
E2198
Pilot Trial of Paclitaxel-Herceptin Adjuvant Therapy for Early Stage Breast Cancer
E3198
A Safety and Efficacy Study of Doxil and Taxotere +- Herceptin in Advanced Breast Cancer
N9831
Phase III Trial of Doxorubicin and Cyclophosphamide (AC) Followed by Weekly Paclitaxel with or without Trastuzumab as Adjuvant Treatment for Women with HER-2 Over-Expressing or Amplified Node Positive or High Risk Node Negative Breast Cancer
NCCTG-98-32-52
Phase II Trial of Paclitaxel, Carboplatin and Trastuzumab (Herceptin(?) as First-Line Chemotherapy in Patients with
Internet

caBIG community contributions

- Infrastructure
  - Ontologies
  - Databases
- Applications
  - Clinical trials support
  - Analytic tools
  - Data mining
- Data
  - Trials
  - Experimental outcomes
    - Genomic
    - Microarray
    - Proteomic

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cancer.gov

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caBIG cancer Biomedical Informatics Grid

HOME | OVERVIEW | PROGRESS | PILOT STRUCTURE | WORKSPACES | INVENTORY

News/Events

- News
  - February 19,20 2004 caBIG Workspace and Working Group Kickoff meeting
  - caBIG featured in NCI Cancer Bulletin
  - caBIG Interactive Overview
  - NEW caBIG Online Forum
  - caBIG Program Updates
  - caBIG FAQs
  - The NCI Director's Corner
  - Dowload caBIG Seminar PowerPoint Presentations

Related Links

- NCICB Site

About caBIG

To expedite the cancer research communities' access to key bioinformatics platforms the NCI plans to deploy an integrating biomedical informatics infrastructure: the cancer biomedical informatics grid (caBIG). In partnership with the cancer research community, the NCI is creating a common, extensible informatics platform that integrates diverse data types and supports interoperable analytic tools. This platform will allow research groups to tap into the rich collection of emerging cancer research data while supporting their individual investigations.

Overview
caBIG at a GLANCE - Overview of Activities and Accomplishments to Date.

Progress
Selecting Pilot Center Participants.

Pilot Structure
Proposed Pilot Structure and Management Approach.

Workspaces
Areas or virtual environments where caBIG pilot project activities will be grouped.

Inventory
Infrastructure, Applications, and Datasets used to support the caBIG initiative.

Please send comments and suggestions to ncicb@pop.nci.nih.gov • Privacy Notice • Accessiblity information

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