CIViC - Clinical Interpretations of Variants in Cancer

www.civicdb.org
http://www.nature.com/ng/journal/v49/n2/full/ng.3774.html
CIViC Homepage

Aim Statement

Recent Activity

Curation

Stats

Educating for best practices in clinical cancer genomics
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- Glossary of Terms:
  - Evidence levels – A, B, C, D, E
  - Evidence types – Diagnostic, Predictive, Predisposing, Prognostic
  - Evidence/trust ratings – 1 - 5 stars
  - Various therapeutic terms
  - Commonly used terms
  - Abbreviations
# Evidence Level Definitions

<table>
<thead>
<tr>
<th>Level</th>
<th>Definition</th>
<th>Examples and further comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A</strong></td>
<td>Proven/consensus association in human medicine.</td>
<td>&quot;AML with mutated NPM1&quot; is a provisional entity in WHO classification of acute myeloid leukemia (AML). This mutation should be tested for in clinical trials and is recommended for testing in patients with cytogenetically normal AML. Validated associations are often in routine clinical practice already or are the subject of major clinical trial efforts.</td>
</tr>
<tr>
<td><strong>B</strong></td>
<td>Clinical trial or other primary patient data supports association.</td>
<td>BRAF V600E is correlated with poor prognosis in papillary thyroid cancer in a study of 187 patients with PTC and other thyroid diseases. The evidence should be supported by observations in multiple patients. Additional support from functional data is desirable but not required.</td>
</tr>
<tr>
<td><strong>C</strong></td>
<td>Individual case reports from clinical journals.</td>
<td>A single patient with FLT3 over-expression responded to the FLT3 inhibitor sunitinib. The study may have involved a large number of patients, but the statement was supported by only a single patient. In some cases, observations from just a handful of patients (e.g. 2-3) or a single family may also be considered a case study/report.</td>
</tr>
<tr>
<td><strong>D</strong></td>
<td>In vivo or in vitro models support association.</td>
<td>Experiments showed that AG1296 is effective in triggering apoptosis in cells with the FLT3 internal tandem duplication. The study may have involved some patient data, but support for this statement was limited to in vivo or in vitro models (e.g. mouse studies, cell lines, molecular assays, etc.).</td>
</tr>
<tr>
<td><strong>E</strong></td>
<td>Indirect evidence.</td>
<td>CD33 and CD123 expression were significantly increased in patients with NPM1 mutation with FLT3-ITD, indicating these patients may respond to combined anti-CD33 and anti-CD123 therapy. The assertion is at least one step removed from a direct association between a variant and clinical relevance.</td>
</tr>
</tbody>
</table>
Trust Ratings

• **1-star**: Evidence likely does not belong in CIViC. Claim is not supported well by experimental evidence. Results are not reproducible, or have very small sample size. No follow-up is done to validate novel claims.

• **2-stars**: Evidence is not well supported by experimental data, and little follow-up data is available. Publication is from a journal with low academic impact. Experiments may lack proper controls, have small sample size, or are not statistically convincing.

• **3-stars**: Evidence is convincing, but not supported by a breadth of experiments. May be smaller scale projects, or novel results without many follow-up experiments. Discrepancies from expected results are explained and not concerning.

• **4-stars**: Strong, well supported evidence. Experiments are well controlled, and results are convincing. Any discrepancies from expected results are well-explained and not concerning.

• **5-stars**: Strong, well supported evidence from a lab or journal with respected academic standing. Experiments are well controlled, and results are clean and reproducible across multiple replicates. Evidence confirmed using separate methods.
# Evidence Classification and Downstream Clinical Significance

## Evidence Classification Matrix

<table>
<thead>
<tr>
<th>Evidence Level</th>
<th>Evidence Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Predictive</td>
</tr>
<tr>
<td>B</td>
<td>Prognostic</td>
</tr>
<tr>
<td>C</td>
<td>Diagnostic</td>
</tr>
<tr>
<td>D</td>
<td>Preclinical</td>
</tr>
<tr>
<td>E</td>
<td>Inferential</td>
</tr>
</tbody>
</table>

The matrix is divided into sections based on clinical relevance and actionability:

- **Clinical Relevance**:
  - More (left side)
  - Less (right side)

- **Actionability**:
  - High (top)
  - Low (bottom)

Each cell in the matrix represents a specific evidence level and type, illustrating its relevance and actionability.

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**Educating for best practices in clinical cancer genomics**
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• API (application programming interface) endpoints open to public use.
  – meant to operate over multiple programming languages.
  – Increases accessibility over various systems.
    • HTTP
    • Many programming languages
    • Command Line
What other genomic applications interact with CIViC?

- Agilent Cartegenia Workbench
- BioG PS
- cBioPortal
- DoCM
- UCSC Browser
- Solve Bio
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- **Data Releases**: Nightly updates, data archived monthly.
  - **Gene Summaries** – i.e. PTEN, IDH1
    - Includes URL to gene page and gene summary in cancer context
  - **Variant Summaries** – i.e. IDH1 R132H
    - Includes genomic coordinates (GRCh37/hg19)
    - Includes reference/variant bases for SNVs
    - Includes transcript information (ENST format)
  - **Variant Group Summaries** – i.e. ALK fusions
  - **Evidence Summaries** – each individual primary publication referenced in CIViC = evidence
    - Includes row in .TSV per publication per variant
      - Includes Citation and PMID
      - Evidence Summary in table format
      - All Gene/Variant/Evidence information, including genomic coordinates, base information for SNVs, and URLs
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• Meeting and Events
  – Annual Hackathon and Jamboree
    • Open to the crowd-sourcing public
    • Location and date of next Hackathon and Jamboree TBD
Links at Bottom of Homepage

• Statistics – Pie Charts summarize
  – Evidence – the nature of primary literature used and curation stats
  – Drugs – drugs with information in CIViC.
  – Disease – list of diseases documented in CIViC.
  – Sources Used – Journals that have contributed primary papers to CIViC.

• Contact – lists creators, developers, curators, PI, funding contributors.
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Data and Knowledge Production

Millions of raw sequence reads are produced for a patient tumor.

Sequences are aligned to the reference genome and tumor-specific events predicted.

Data are reviewed and validation experiments performed to identify high quality events.

Events are annotated and scored in an effort to predict events of functional significance.

CIViC Curation

Crowdsourced curation efforts, moderated by experts in oncology and bioinformatics, help to build a knowledgebase of clinical interpretations of variants in cancer, describing the therapeutic, prognostic, diagnostic, and predisposing relevance of inherited and somatic variants of all types. Anyone may sign up to be a curator, add evidence, suggest changes to records, and discuss ongoing curation efforts.

Research Gene, Variant, & Evidence Summaries

A genome analyst uses CIViC's summaries to interpret and prioritize functionally significant events in the context of published literature, clinical trials, and linked knowledgebases.

Pathologists and oncologists review analysts' reports to help evaluate the significance of potentially clinically actionable events and incorporate into patient care.
### Educating for best practices in clinical cancer genomics

#### Using ‘Browse’ Option

![CIVIC Browser](image)

**Various Search Criteria on Variants and Genes tabs**

<table>
<thead>
<tr>
<th>Variant</th>
<th>Entráz Gene</th>
<th>Diseases</th>
<th>Drugs</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>AMPLIFICATION</td>
<td>ERBB2</td>
<td>Uterine Corpus Serous Adenocarcinoma</td>
<td>A66, AKT1/2, Afinatinib, Capetabibine, Cetux</td>
<td>51</td>
</tr>
<tr>
<td>V600E</td>
<td>BRAF</td>
<td>Thyroid Cancer, Skin Melanoma, Papillary</td>
<td>BEZ235 (VNP-BEZ235, Dactolitab, Bevac</td>
<td>47</td>
</tr>
<tr>
<td>EXON 12 MUTATION</td>
<td>NPM1</td>
<td>Acute Myeloid Leukemia</td>
<td>All-trans Retinoic Acid, Anti-CD123, Anti-CD</td>
<td>39</td>
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<tr>
<td>R882</td>
<td>DNMT3A</td>
<td>Acute Myeloid Leukemia</td>
<td>Daunorubicin, Idarubicin</td>
<td>28</td>
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<td>ITD</td>
<td>FLT3</td>
<td>Acute Promyelocytic Leukemia, Acute M...</td>
<td>A01209, All-trans Retinoic Acid, Anthracy...</td>
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<tr>
<td>MUTATION</td>
<td>Kras</td>
<td>Pseudomyoma Peritonei, Pancreatic Ad...</td>
<td>AZD5363, AZD8186, Afinatinib, BAY 86-976, ...</td>
<td>25</td>
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<tr>
<td>LOSS</td>
<td>PTEN</td>
<td>Stomach Carcinoma, Stomach Cancer, Pr...</td>
<td>AZD5363, AZD8186, BYL719 (Alpelisib), B...</td>
<td>23</td>
</tr>
<tr>
<td>T790M</td>
<td>EGFR</td>
<td>Non-small Cell Lung Carcinoma, Lung Ca...</td>
<td>AEE788, Afinatinib, Dacomitinib, Erlotinib, ...</td>
<td>21</td>
</tr>
<tr>
<td>ALK FUSIONS</td>
<td>ALK</td>
<td>Non-small Cell Lung Carcinoma, Lung Ad...</td>
<td>Alectinib (CH5424802, CH5424802, Cert...</td>
<td>21</td>
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<tr>
<td>MUTATION</td>
<td>TP53</td>
<td>Precursor B Lymphoblastic Lymphoma/L</td>
<td>Alectinib, Chemotherapy, Docetaxer</td>
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<tr>
<td>MUTATION</td>
<td>PIK3CA</td>
<td>Stomach Cancer, Her2-receptor Positive...</td>
<td>17-AAD, AZD5363, Anti-EGFR Monoclon</td>
<td>18</td>
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<tr>
<td>EXPRESSION</td>
<td>CD274</td>
<td>Stomach Carcinoma, Papillary Thyroid Ca...</td>
<td>Atezolizumab, Avelumab, Ipilimumab, Niv</td>
<td>14</td>
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<tr>
<td>AMPLIFICATION</td>
<td>FGFR1</td>
<td>Non-small Cell Lung Carcinoma, Lung Sq...</td>
<td>4-hydroxytamoxifen, BOS-308, BOS-398, D...</td>
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<td>MUTATION</td>
<td>NRAS</td>
<td>Skin Melanoma, Multiple Myeloma, Mela...</td>
<td>Amnatinib, Binimetinib (MEK162), Cetux</td>
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<td>H1047R</td>
<td>PIK3CA</td>
<td>Thyroid Cancer, Lung Adenocarcinoma, H...</td>
<td>AZD5363, BEZ235 (VNP-BEZ235, Dactolitab</td>
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<tr>
<td>V600E</td>
<td>BRAF</td>
<td>Non-small Cell Lung Carcinoma, Melanoma</td>
<td>BAY 86-9760, Cetuximab, Dabrafenib, Pia</td>
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<tr>
<td>AMPLIFICATION</td>
<td>MET</td>
<td>Non-small Cell Lung Carcinoma, Lung Sq...</td>
<td>Crizotinib, Erlotinib, Gefitinib, Onanizum</td>
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<td>p10 EXPRESSION</td>
<td>CDKN2A</td>
<td>Oropharynx Cancer, Non-small Cell Lung</td>
<td>Afinatinib, Cetuximab, EGFR Inhibitor, Pani</td>
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<tr>
<td>MUTATION</td>
<td>BRCA1</td>
<td>Triple-receptor Negative Breast Cancer, O...</td>
<td>Carboplatin, Cisplatin, Cisplatin, Olaparib</td>
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<td>EXON 19 DELETION</td>
<td>EGFR</td>
<td>Non-small Cell Lung Carcinoma, Lung Ad...</td>
<td>Afinatinib, Erlotinib, Gefitinib</td>
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<tr>
<td>L858R</td>
<td>EGFR</td>
<td>Non-small Cell Lung Carcinoma, Lung Ad...</td>
<td>Afinatinib, Erlotinib, Gefitinib</td>
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<tr>
<td>EXON 2 MUTATION</td>
<td>KRAS</td>
<td>Pancreatic Carcinoma, Pancreatic Cance...</td>
<td>Cetuximab, EGFR Inhibitor, Erlotinib, Gelf</td>
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<tr>
<td>MUTATION</td>
<td>BRCA2</td>
<td>Triple-receptor Negative Breast Cancer, O...</td>
<td>Carboplatin, Cisplatin, Cisplatin, Olaparib</td>
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<td>EXON 7 MUTATION</td>
<td>WT1</td>
<td>Acute Myeloid Leukemia</td>
<td>Cytarabine, Daunorubicin</td>
<td>9</td>
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<tr>
<td>G12D</td>
<td>KRAS</td>
<td>Tumor Of Exocrine Pancreas, Pancreatic...</td>
<td>ARRY-142886, Adoptive T-cell Transfer, B...</td>
<td>9</td>
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</tbody>
</table>
### Variant Groups

<table>
<thead>
<tr>
<th>Name</th>
<th>Variants</th>
<th>Count</th>
<th>Genes</th>
<th>Evidence Items</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALK Fusions</td>
<td>RANBP2-ALK, NPM-ALK, EML4-ALK L1196M, EML4-ALK E5...</td>
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<td>ALK</td>
<td>58</td>
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<td>EGFR TKI Resistance</td>
<td>T790M, G12D, G12C, G12A</td>
<td>4</td>
<td>EGFR, KRAS</td>
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<td>NPM1 Exon 12</td>
<td>W288FS, EXON 12 MUTATION</td>
<td>2</td>
<td>NPM1</td>
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<tr>
<td>Other V600's</td>
<td>V600K, V600E+V600M, V600D, V600I, L597R</td>
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<td>BRAF</td>
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<tr>
<td>Imatinib Resistance</td>
<td>I843DEL, D842I/D842V/M, D842Y, D842V, D842I, BCR-ABL T3...</td>
<td>8</td>
<td>ABL1, PDGFRA</td>
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<tr>
<td>Crizotinib Resistance</td>
<td>F1174L, EML4-ALK S1260Y, EML4-ALK L1196M, EML4-ALK E5...</td>
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<td>ALK</td>
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<tr>
<td>KIT Exon 11</td>
<td>V654A, L576P, INTERNAL DUPLICATION, EXON 11 MUTATION, KIT D822Y</td>
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<td>KIT</td>
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<tr>
<td>BRAF Fusions</td>
<td>ZKSCAN1-BRAF, TRIM24-BRAF, PPFIBP2-BRAF, PAPSS1-BRAF, PAPSS1-2...</td>
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<td>BRAF</td>
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<td>SYT-SSX fusions</td>
<td>SS18-SSX4, SS18-SSX2, SS18-SSX1</td>
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<td>SSX1, SSX2, SSX4</td>
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<tr>
<td>ESR1 Ligand/Binding Domain</td>
<td>Y537S, Y537N, Y537C, L536Q, D538G</td>
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<td>ESR1</td>
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<tr>
<td>HER2 Activating</td>
<td>V842I, V777L, R896C, P780INS, G309A, D769Y, D769H</td>
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<td>ERBB2</td>
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<tr>
<td>BRCA Germline Variants</td>
<td>LOSS-OF-FUNCTION</td>
<td>1</td>
<td>BRCA1, BRCA2</td>
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<tr>
<td>Motesanib Resistance</td>
<td>M918T, G634W</td>
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<td>RET</td>
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<tr>
<td>FGFR fusions</td>
<td>FGFR3-BALAP2L1, FGFR2-TACC3, FGFR2-MGEA5</td>
<td>3</td>
<td>FGFR2, FGFR3</td>
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<tr>
<td>Kinase Dead BRAF Mutation</td>
<td>K483M, D594V, D594A</td>
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<td>BRAF</td>
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<tr>
<td>TSC Loss</td>
<td>LOSS-OF-FUNCTION, FRAMESHIFT TRUNCATION</td>
<td>2</td>
<td>TSC1</td>
<td>3</td>
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<tr>
<td>KIT Exon 17</td>
<td>D816V</td>
<td>1</td>
<td>KIT</td>
<td>3</td>
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<tr>
<td>PTEN Loss-of-Function</td>
<td>R233*</td>
<td>1</td>
<td>PTEN</td>
<td>2</td>
</tr>
<tr>
<td>HEAT domain mutation</td>
<td>K700E, K666N</td>
<td>2</td>
<td>SF3B1</td>
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</tr>
</tbody>
</table>
Gene Page

Educating for best practices in clinical cancer genomics
Scenario #1

• You are a laboratory professional designing new disease specific clinical NGS panels.
  – What genes do you include in your Acute Myeloid Leukemia panel?
  – What diseases are best supported by CIViC?
What Disease are best supported by CIViC?

* Click on “Statistics” link at bottom of home page to see this bar graph and other data.
Scenario #1

• You are a laboratory professional designing new disease specific clinical NGS panels.
  – What genes do you include in your Acute Myeloid Leukemia panel?
  – What diseases are best supported by CIViC?
Find Genes and Variants Associated with Disease of Interest: Option #1 “Search”

- Using “Search” match the disease name to your disease of interest under the ‘Evidence’ tab.
- Can export data from table as .CSV.
- Select any gene/variant from the list to view in more detail.
Find Genes and Variants Associated with Disease of Interest: Option #1 “Browse”

- Using “Browse”, type in your disease of interest into the designated box in the variants tab or the genes tab.
- If you search under the genes tab, you won’t have genes duplicated on the list but you lose variant information.
- Not able to export list as .CSV
- Select any gene/variant from the list to view in more detail.
Educating for best practices in clinical cancer genomics
Reference back to PMID/other CIViC entries from same citation

- Click on Citation link on bottom of gene/variant page.
- Evidence Summary page has article information and abstract
- List of Evidence items associated with primary publication near bottom of page.
Scenario #2

- You are trying to interpret a complex WES report on an ovarian cancer patient.
  - How do you narrow down pathogenic variants that may be actionable in your patient’s report?
  - TP53 – P72R
  - PIK3CA – amplification
  - AKT1 – E17K
  - AKT2 – amplification
  - CBFB – mutation
  - CASP8 – D302H
Search Gene/Variant Pages for Therapeutic Information

PIK3CA Variants

VARIANT AMPLIFICATION

This Variant does not currently have a Summary.

Variant Type:
Transcript Amplification

HGVS Expression:
None specified.

ClinVar ID:
N/A

Evidence for AMPLIFICATION 4 total items

<table>
<thead>
<tr>
<th>EID</th>
<th>DESC</th>
<th>DIS</th>
<th>DRUGS</th>
<th>EL</th>
<th>ET</th>
<th>ED</th>
<th>CS</th>
<th>VO</th>
<th>TR</th>
</tr>
</thead>
<tbody>
<tr>
<td>504</td>
<td>In patients with gastric cancer...</td>
<td>Gastric Adenocarcinoma</td>
<td>N/A</td>
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<td></td>
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<td>756</td>
<td>One platinum-refractory epithelial...</td>
<td>Epithelial Ovarian Cancer</td>
<td>Pictilisib</td>
<td>C</td>
<td></td>
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<tr>
<td>1403</td>
<td>474 cancer cell lines from the...</td>
<td>Stomach Carcinoma</td>
<td>EYL719 (Alpelisib)</td>
<td>D</td>
<td></td>
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<tr>
<td>1464</td>
<td>The HNSCC cell line LB771 with...</td>
<td>Head And Neck Squamous Cell</td>
<td>Taselisib (GDC-0032)</td>
<td>D</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Scenario #2 - Results

• You are a laboratory consultant with a complex WES report on an ovarian cancer patient.
  – How do you narrow down pathogenic variants that may be actionable in your patient’s report?
    • TP53 – P72R
    • PIK3CA – amplification
    • AKT1 – E17K
    • AKT2 – amplification
    • CBFB – mutation
    • CASP8 – D302H
Scenario #3

• You have been given the task of putting together a Pan Cancer List for your laboratory/institution.
  – Which genes should be included in your list?
Pan Cancer List

• All variants/genes/rearrangements documented in CIViC are evidence-based.

• Do you want to include all genes from CIViC?
  – If so, document in your own internal database that these entries to your Pan Cancer List are described in CIViC.
  • Include links to CIViC if possible
• Download desired data release from CIViC
  – Click on Data Release in bottom banner.
  – Select appropriate .TSV file
    • Likely gene and/or variant file.
  – Add to pan cancer list format of choice
Scenario #4

- You would like to see all possible high quality evidence pertaining to treatment for colorectal cancer patients with NRAS mutation.
  - Advanced Search
    - Gene Name: NRAS
    - Trust Rating: greater than or equal to 3 stars
    - Evidence Level: above C – Case Study
    - Disease Name: Colorectal Cancer (DOID: 9256)
* Start with an Example Search if your query is similar

* Enter, add, or remove search criteria to match your query

* Look for evidence items with drugs identified.
Scenario #5

- You are looking into creating a genomic knowledgebase for your institution.
  - How can you create a symbiotic relationship between your knowledgebase and CIViC?
    - Use links to CIViC in your knowledgebase
    - Use CIViC API – find information on bottom banner “API Documentation” (See slide 6)
    - Cite CIViC whenever applicable (See slide 1)
    - Join the CIViC crowd-source curation efforts
    - Join VICC – Variant Interpretation in Cancer Consortium (http://cancervariants.org/)
Joining CIViC Community

- Sign up with Google account using button in upper right hand corner.
  - Link account to Twitter, Facebook, LinkedIn
  - Activity will be tracked by CIViC moderators
# CIViC Assessment of Knowledgebase Silos

<table>
<thead>
<tr>
<th></th>
<th>Cancer Genome Interpreter (CGI)</th>
<th>CanDL (CDL)¹</th>
<th>Gene Drug Knowledge Database (GDKD)²</th>
<th>OncoKb (OKB)</th>
<th>Precision Medicine Knowledge base (PMKB)</th>
<th>Jackson Knowledge base (JKB)³</th>
<th>My Cancer Genome (MCG)⁴</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total unique publications</td>
<td>530</td>
<td>126</td>
<td>409</td>
<td>3,700</td>
<td>560</td>
<td>787</td>
<td>840</td>
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<tr>
<td>Percentage of publications in this resource found in CIViC</td>
<td>21.9%</td>
<td>24.6%</td>
<td>26.9%</td>
<td>6.8%</td>
<td>6.6%</td>
<td>8.6%</td>
<td>14.9%</td>
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<tr>
<td>Percentage of publications in CIViC found in this resource</td>
<td>13.0%</td>
<td>3.4%</td>
<td>12.3%</td>
<td>1.6%</td>
<td>4.1%</td>
<td>7.6%</td>
<td>14.0%</td>
</tr>
<tr>
<td>Total overlapping publications with CIViC</td>
<td>116</td>
<td>30</td>
<td>110</td>
<td>61</td>
<td>37</td>
<td>68</td>
<td>125</td>
</tr>
<tr>
<td>Maximum overlapping publications with any other resource</td>
<td>293 (55.3%) (GDKD)</td>
<td>38 (30.2%) (MCG)</td>
<td>293 (71.6%) (CGI)</td>
<td>91 (2.5%) (PMKB)</td>
<td>91 (16.3%) (OKB)</td>
<td>73 (9.3%) (MCG)</td>
<td>125 (14.9%) (CIViC)</td>
</tr>
</tbody>
</table>
CIViC Video Tutorials

- https://www.youtube.com/watch?v=TP_a1za7gJQ
- https://www.youtube.com/watch?v=d6mjtzwwrA
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