Non-NAACCR Standard Data Items
Biomarkers

Comparative Effectiveness Research Project

NHSCR
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Types of BCR-ABL Biomarkers

There are four types of BCR-ABL biomarkers:

- **Cytogenetic**
  - Karyotyping
  - Conventional cytogenetics
  - Philadelphia chromosome analysis
  - Chromosomal banding analysis

- **Fluorescence in Situ Hybridization (FISH)**

- **Qualitative Reverse Transcriptase Polymerase Chain Reaction (RT-PCR Qual)**

- **Quantitative Reverse Transcriptase Polymerase Chain Reaction (RT-PCR Quant)**
  - Real time RT-PCR
  - BCR-ABL Gene Rearrangement Analysis
Biomarkers: BCR-ABL

- Required for Chronic Myeloid Leukemia (CML)
- Refers to all BCR-ABL transcriptions, including BCR-ABL2
- Biomarker analysis may be used to monitor disease response to therapy and relapse
- Record results of analysis for BCR-ABL t(9;22) (q34;q11) at time of initial diagnosis
- If multiple tests done, use results closest to the diagnosis date

DO NOT RECORD TEST RESULTS AFTER INITIATION OF TX
# Coding Instructions

<table>
<thead>
<tr>
<th>Code</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>000*</td>
<td>Negative result OR Not applicable (e.g. information not collected for this case) OR Test not done (e.g., test not ordered and was not performed) OR Unknown information (e.g., not documented in source record) OR Test ordered (e.g., results not in source records)</td>
</tr>
<tr>
<td>010</td>
<td>Positive: code only for cytogenetic, FISH, RT-PCR Qual *used in combination with the corresponding BCR-ABL related date and date flag variables to substantiate reason for coding “000”</td>
</tr>
</tbody>
</table>

For RT-PCR Quant, record the exact ratio*:

| 001-998 | Ratio of 0.001 to 0.998 (enter exact ratio) |
| 999     | Ratio greater than or equal to 0.999 |

*Units reported as ratio of fusion gene transcript to β-2-microgloblin reference gene transcript.
Biomarkers: BCR-ABL Date and Date Flag

- Records the date of the BCR-ABL test
- Use date that specimen was obtained and sent for analysis, NOT the report date
- Again, do not record results of this test after initiation of treatment.
- Date Flags: Explains why there is no appropriate value in date fields
## Biomarkers: BCR-ABL Date Flags

<table>
<thead>
<tr>
<th>Code</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>No information</td>
</tr>
<tr>
<td>11</td>
<td>Not applicable</td>
</tr>
<tr>
<td>12</td>
<td>Value applicable but unknown</td>
</tr>
<tr>
<td>15</td>
<td>Information not available now, but expected later</td>
</tr>
<tr>
<td>Blank</td>
<td>Valid date provided, or date not expected to have been transmitted</td>
</tr>
</tbody>
</table>

Comment: This is consistent with part of the initiative of the transformation from the old NAACCR date standards to interoperable dates.
Thank You

NHSCR is supported by the Centers for Disease Control and Prevention's National Program of Cancer Registries (NPCR) through cooperative agreement U58/DP000798 awarded to the New Hampshire Department of Health and Human Services, Division of Public Health Services, Bureau of Disease Control and Health Statistics, Health Statistics and Data Management Section. The contents of this website are solely the responsibility of NHSCR and do not necessarily represent the official views of the Centers for Disease Control and Prevention.

Strict policies and procedures have been developed to maintain confidentiality in disclosure of data.