# NOVARTIS

# Help With Identifying Ph+ CML-CP Patients for Treatment Evaluation

This Guide Provides an Overview for Using Reporting Workbench Patient Reports and BestPractice Advisories (BPAs) to Help Identify Ph+ CML-CP Patients for Evaluation.

Ph+ CML-CP, Philadelphia Chromosome Positive Chronic Myeloid Leukemia Chronic Phase.
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# Using This Guide and EHR Worksheets

This Guide is not intended to provide any clinical advice or recommendations, which are solely the responsibility of the health system. Please see the important statistics on the following pages that highlight the unmet needs of CML patients who are struggling with drug resistance, unmanageable side effects, or other suboptimal results with treatment.

This Guide can help clinical decision makers implement automated EHR functionalities to identify and evaluate care for Ph+ CML-CP patients who may benefit from a treatment switch. It provides examples of Reporting Workbench Patient Reports and BPAs, along with EHR Worksheets. Theworksheets provide a list of criteria and/or actions to consider including when creating Reporting Workbench Patient Reports and BPAs. The EHR Worksheet can be customized, saved, and reused. It does not constitute guidance for medical advice or treatment.
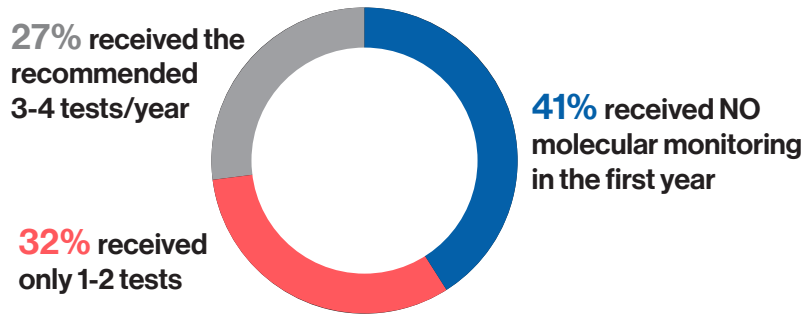
The information listed in this Guide is based upon the most recent version of Epic. Functions and features may change as new software versions are released. The Guide and EHR Worksheets are meant to serve as educational examples only and should not replace detailed instructions provided to you by your internal or external EHR support resources. Screen images shown within represent hypothetical screens in Epic. Novartis makes no claims or warranties about the applicability or appropriateness of this information and does not endorse specific EHR systems.

EHR, Electronic Health Record.

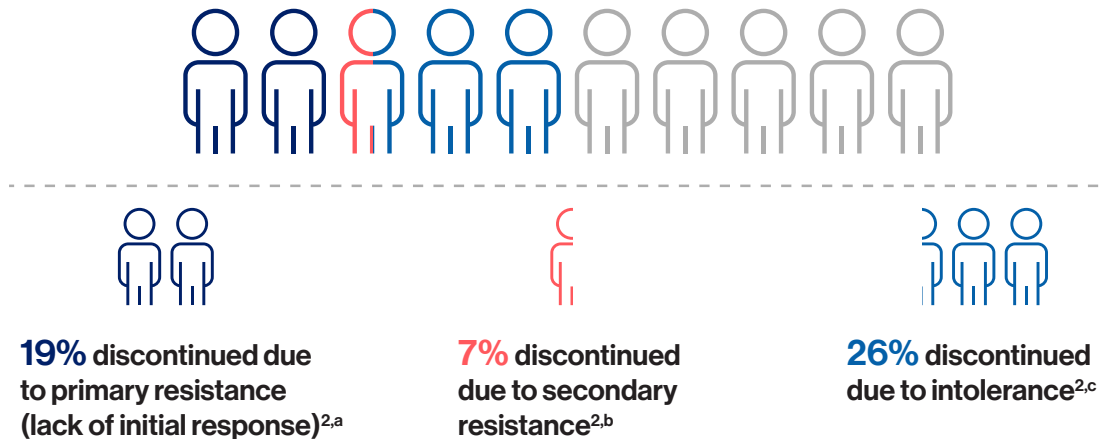# Real-world evidence reveals significant underutilization of molecular monitoring

**A claims database review of 1205 patients with newly diagnosed CML found that[1]:**

**27%** received the recommended 3-4 tests/year

**41%** received NO molecular monitoring in the first year

**32%** received only 1-2 tests

Studies suggest that <30% of patients with CML are monitored according to clinical practice guidelines during the first year of TKI treatment.[1]

# Lack of initial response, resistance, and intolerance are key drivers of treatment discontinuation of TKI therapy

**In a study of 119 patients with CML-CP treated with 2L TKIs, 52% discontinued 2L TKI due to resistance or intolerance[2]**

**19%** discontinued due to primary resistance (lack of initial response)[2,a]

**7%** discontinued due to secondary resistance[2,b]

**26%** discontinued due to intolerance[2,c]

TKI, Tyrosine Kinase Inhibitor.

[a]Primary resistance is defined as lack of efficacy (failure to achieve landmark responses) from the onset of treatment.[3]
[b]Secondary resistance, also known as acquired resistance, is considered loss of response to treatment.[4]
[c]Intolerance is considered when a patient develops an adverse event that cannot be managed through dose reduction or treatment of symptoms.[5]

Treatment intolerance may lead to nonadherence in patients receiving TKI therapy

# Treatment intolerance may lead to nonadherence in patients receiving TKI therapy

### Some patients are intolerant to TKIs,

with up to ~25% of patients discontinuing treatment due to an adverse event[6]

### Up to ~30% of patients with CML are nonadherent.[7]

Nonadherence may be a factor associated with higher health care costs, suboptimal response, disease progression, and mortality[8-10]

# EHR Capabilities Can Help to Stratify CML Patients

Clinical champions within an organization can advocate for the configuration of EHR capabilities such as Reporting Workbench Patient Reports and BPAs.

## Role of Reporting Workbench Patient Reports

Reporting Workbench Patient Reports can be used to demonstrate and champion the need for follow-up care within an organization. They can also be used for planning purposes to understand for which patients a BPA would display.

Available criteria to generate these reports can include patient gender, age, diagnosis, lab result values, and medications.

| Reports | | | | | | ✕ |
|---------|---|---|---|---|---|---|
| **CML Patients With out-of-range BCR::ABL lab values** | | | | | | |
| Patient ID [MRN] | Name | DOB | Gender | Insurance coverage | Date | Value |
| 8013335459 | Smith, Betty | 11/1/1933 | F | Blue Cross | 2/3/2023 | 0.0178 |
| | | | | | 12/28/2022 | 0.0189 |
| | | | | | 11/18/2022 | 0.0198 |
| 8013345789 | Jones, Sam | 5/4/1988 | M | Blue Shield | 4/20/2023 | 0.0137 |
| | | | | | 3/15/2023 | 0.0156 |
| | | | | | 1/20/2023 | 0.0198 |
| 8013238521 | Abner, Darlene | 11/25/1970 | F | Anthem | 6/20/2023 | 0.0142 |
| | | | | | 5/10/2023 | 0.0169 |
| 8013208132 | Carlson, Sandra | 4/23/1974 | F | United | 6/14/2023 | 0.0165 |
| | | | | | 6/5/2023 | 0.0192 |
| | | | | | 5/1/2023 | 0.0198 |

*Hypothetical example of a Reporting Workbench Patient Report*

Note: In Epic, a Reporting Workbench Patient Report can be created by the EHR support team and saved to the requester's My Reports folder for on-demand running or scheduling.

# EHR Capabilities Can Help to Stratify CML Patients (continued)

## Role of BPAs

As part of an organization's care quality EHR initiative, BPAs can help proactively identify at-risk Ph+ CML-CP patients with unmet needs when they come in for an appointment.

BPAs can be configured in a meaningful way which specifies the patient criteria and milestones within the EHR workflow, provider types (eg, health care professionals, care managers), and clinical actions.

| BestPractice Advisory | | |
|---|---|---|
| ⚠ **This patient is diagnosed with Ph+ Chronic Myeloid Leukemia in chronic phase and has out-of-range BCR::ABL results. Evaluate patient chart based on the following:** | | |

C92.10 - chronic myeloid leukemia, BCR::ABL positive
21821-4  -  t(9,22)(ABL1,BCR) Translocation [Presence] in Blood or Tissue by Molecular genetics method
BCR::ABL 0.0137  4/20/23
BCR::ABL 0.0156  3/15/23
BCR::ABL 0.0198  1/20/23

| Open CML SmartSet | Do Not Open | Open the CML SmartSet |
|---|---|---|
| Order Labs | Do Not Order | Order BCR::ABL |
| Add Visit Diagnosis | Do Not Add | Leukemia in relapse (HCC) |

Accept    Cancel

*Hypothetical example of a BestPractice Advisory*

BCR, breakpoint cluster region; ABL, Abelson.

# Optional Use of EHR Worksheets in This Guide

An interactive, digital EHR Worksheet that follows is intended to assist health systems in configuring their EHR capabilities to help identify Ph+ CML-CP patients in need of additional care. It outlines the criteria that need to be defined in an IT request for creating Reporting Workbench Patient Reports and BPAs.

The EHR Worksheet can help translate desired clinical parameters for identifying CML patients with suboptimal results from CML treatment into categories and values for EHR functions. Once the EHR Worksheet is completed, it can be saved under a new name. Then, the EHR Worksheet can be reused or edited if the criteria selected results in a patient population that is too broad or too narrow.

The codes are provided for reference purposes only and may not be all inclusive. The responsibility to determine coverage and reimbursement parameters, and appropriate coding for a particular patient and/or procedure, is always the responsibility of the physician. The EHR Worksheet includes categories of selection criteria for health systems to consider when seeking to identify and evaluate appropriate patients.

## Actions for a clinical champion:

**1**

Start by selecting the inclusion and exclusion criteria to define the specific search parameters for finding and evaluating CML patients with suboptimal results from CML treatment.

**2**

Then, specify the data that will be displayed on the Reporting Workbench Patient Report by selecting columns for provider evaluation and review. After reviewing the Reporting Workbench Patient Report, clinical champions may wish to broaden or narrow the criteria and values to refine the list of patients according to their preferences.

**3**

Utilizing the criteria in Step 1, choose the language, display restrictions, and clinical actions for the BPA, that will appear to prompt treatment evaluation by care team members..

## The following pages help identify TKI-resistant and/or intolerant patients with specific criteria:

| Patients with a missing or overdue BCR::ABL test | Patients who are non-compliant with TKI medication prescriptions that have lapsed | Patients who are not meeting treatment milestones and may be TKI-resistant | Patients who are struggling with side effects and may be TKI-intolerant |

# Patient With a Missing or Overdue BCR::ABL Test

Before you begin to build on this topic, it's important to consider several key technical questions that will influence the impact of your BCR::ABL program.

### Technical Considerations:

**Are results interfaced back to your EHR?**

| OPTION | ACTIONS |
|---|---|
| **Yes** – our results interface returns BCR::ABL results and completes the original order | Proceed with EHR report and BPA build |
| **No** – we don't receive results digitally to our EHR | Do not proceed with build – pursue an interfaced result option with your interfaces team before moving forward |

**If yes above, are interfaced results filed to discrete result values in your EHR?**

| OPTION | ACTIONS |
|---|---|
| **Yes** – our results interface returns BCR::ABL results and completes the original order | Proceed with EHR report and BPA build |
| **No** – we don't receive results digitally to our EHR | Do not proceed with build – pursue an interfaced result option with your interfaces team before moving forward |

### Operational Impact:

If you are not receiving discrete results for your BCR::ABL tests, the build is still possible but there is a greater operational burden placed upon the program.

Reports that are built to identify patients with missing or overdue results will return patients who have had the order completed but the EHR won't be able to return that data. This places the onus of follow-up onto whoever is managing the reports and the population. In other words, operational owners running these reports will need to do manual follow-up in the chart or with the patient directly to determine if the result was completed and then manually key those results into the patient's chart.

Given the relatively small size of the population who would be doing this testing, this may not be a significant lift and may be worth it for your organization. However, it's important to plan for the additional workload.

# Patient With a Missing or Overdue BCR::ABL Test

## Inclusion Criteria for Patient Report and BPA

| INCLUSION CRITERIA | CATEGORY ("AND" CRITERIA) | ✔ | VALUES | | |
|---|---|---|---|---|---|
| | Patient Status | | Alive | | |
| | Population (select one) | | Only my patients | | |
| | | | Seen in my department | | |
| | | | All patients who meet the criteria | | |
| | | | Other | | |
| | Age (eg ≥18) | | >        < | | |
| | | | | | |
| | Diagnosis/ Clinical Findings (select ≥ 1) "or" criteria | ✔ | **Description** | **Code Set** | **Code[11, 12]** |
| | | | chronic myeloid leukemia, BCR::ABL positive | ICD-10 | C92.10 |
| | | | chronic myeloid leukemia, BCR::ABL positive, in remission | ICD-10 | C92.11 |
| | | | chronic myeloid leukemia, BCR::ABL positive, in relapse | ICD-10 | C92.12 |
| | | | chronic myeloid leukemia, disease; disorder | SNOMED | 92818009 |
| | | | myeloid leukemia in relapse; disorder | SNOMED | 122901000119109 |
| | | | relapsing chronic myeloid leukemia; disorder | SNOMED | 415287001 |
| | | | chronic myeloid leukemia category; morphologic abnormality | SNOMED | 413841000 |
| | | | chronic phase chronic myeloid leukemia; disorder | SNOMED | 413847001 |
| | Lab tests missing or overdue (select a lab test and specify a date range) | ✔ | **Description** | **Code Set** | **Code[13]** |
| | | | t(9,22)(ABL1,BCR) Translocation [Presence] in Blood or Tissue by Molecular genetics method | LOINC | 21821-4 |
| | | | | Local | |
| | | BCR::ABL Date Range Date of BCR::ABL lab result (eg, greater than 6 months is [>m-6]) | | Date range:        - | |

# Patient With a Missing or Overdue BCR::ABL (continued)

## Exclusion Criteria for Patient Report and BPA

<table>
<tr><td rowspan="10" style="writing-mode: vertical-rl">EXCLUSION CRITERIA</td><td><strong>CATEGORY ("AND" CRITERIA)</strong></td><td><strong>✔</strong></td><td colspan="4" align="center"><strong>VALUES</strong></td></tr>
<tr><td rowspan="4"><strong>Patients who have had a BCR::ABL ordered in the past X days</strong></td><td><strong>✔</strong></td><td><strong>Description</strong></td><td colspan="2"><strong>Code Set</strong></td><td><strong>Code[13]</strong></td></tr>
<tr><td></td><td rowspan="2">BCR::ABL1 kinase domain targeted mutation analysis</td><td colspan="2">LOINC</td><td>55135-8</td></tr>
<tr><td></td><td colspan="2">Local</td><td></td></tr>
<tr><td colspan="2">BCR::ABL Order Date Range<br>Timeframe for capturing BCR::ABL order<br>(eg, [m-1] for 30 days)</td><td colspan="2">Date range:</td><td>-</td></tr>
<tr><td rowspan="4"><strong>Patients who have had a BCR::ABL result in the past X days (select a lab test and specify a date range)</strong></td><td><strong>✔</strong></td><td><strong>Description</strong></td><td colspan="2"><strong>Code Set</strong></td><td><strong>Code[13]</strong></td></tr>
<tr><td></td><td rowspan="2">t(9,22)(ABL1,BCR) Translocation [Presence] in Blood or Tissue by Molecular genetics method</td><td colspan="2">LOINC</td><td>21821-4</td></tr>
<tr><td></td><td colspan="2">Local</td><td></td></tr>
<tr><td colspan="2">BCR::ABL Date Range<br>Date of BCR::ABL lab result<br>(eg, greater than 6 months is [>m-6])</td><td colspan="2">Date range:</td><td>-</td></tr>
</table>

# Patient With a Missing or Overdue BCR::ABL (continued)

## Report Output Columns

| CATEGORY | ✔ | VALUES | | |
|---|---|---|---|---|
| **Patient Demographics** | | Patient ID (MRN) | | |
| | | Name | | |
| | | DOB | | |
| | | Phone Number | | |
| | | MyChart Status | | |
| **Diagnosis/ Clinical Findings** | ✔ | **Description** | **Code Set** | **Code[11, 12]** |
| | | chronic myeloid leukemia, BCR::ABL positive | ICD-10 | C92.10 |
| | | chronic myeloid leukemia, BCR::ABL positive, in remission | ICD-10 | C92.11 |
| | | chronic myeloid leukemia, BCR::ABL positive, in relapse | ICD-10 | C92.12 |
| | | chronic myeloid leukemia, disease; disorder | SNOMED | 92818009 |
| | | myeloid leukemia in relapse; disorder | SNOMED | 122901000119109 |
| | | relapsing chronic myeloid leukemia; disorder | SNOMED | 415287001 |
| | | chronic myeloid leukemia category; morphologic abnormality | SNOMED | 413841000 |
| | | chronic phase chronic myeloid leukemia; disorder | SNOMED | 413847001 |
| **Payer** | | Insurance Coverage Name | | |
| **Last Documented BCR::ABL Results** | | LOINC Code | | |
| | | Description | | |
| | | Value | | |
| | | Date | | |
| **Additional Clinical Criteria** | | | | |

REPORT OUTPUT COLUMNS

# Patient With a Missing or Overdue BCR::ABL (continued)

## BPA Content

| | CATEGORY | ✓ | VALUES |
|---|---|---|---|
| **BPA CONTENT** | **BPA Name (eg, Patients with missing/ overdue BCR::ABL.)** | | |
| | **Message to include in BPA (eg, "This patient with CML has missing BCR::ABL lab tests.")** | | |
| | **Data to include in BPA** | | Most recent BCR::ABL lab value |
| | | | Diagnosis |
| | | | Additional Clinical Criteria |
| | **Clinical actions to take based on the BPA** | | CML Order Set Name                              # |
| | | | Order BCR::ABL lab test |
| | | | Order Appropriate Medication |
| | | | Add Diagnosis C92.10 |
| | | | Additional Orderable Items to Include |

# Noncompliant Patient

Before you begin to build on this topic, it's important to consider several key technical questions that will influence the impact of your BCR::ABL program.

## Technical Considerations:

Is medication adherence data returned by your e-prescribing vendor (ie, Surescripts)?

| OPTION | ACTIONS |
|---|---|
| **Yes** – we receive data back from our eRx vendor on fills and other adherence items | Proceed with EHR report and BPA build |
| **No** – we don't receive any med adherence data | Proceed with EHR report and BPA build but note operational impact below |

## Operational Impact:

If you are not receiving TKI medication adherence data back from your vendor, the build is still possible but there is a greater operational burden placed upon the program.

Reports that are built to identify patients with late or missing medication fill data will return patients who may have had the medication filled despite data showing the opposite. This places the onus of follow-up onto whoever is managing the reports and the population. In other words, operational owners running these reports will need to do manual follow-up in the chart or with the patient directly to determine if the medication was filled.

Given the relatively small size of the population, this may not be a significant lift and may be worth it for your organization. However, it's important to plan for the additional workload.

# Noncompliant Patient

## Inclusion Criteria for Patient Report and BPA

| CATEGORY ("AND" CRITERIA) | ✓ | VALUES | | |
|---|---|---|---|---|
| **Patient Status** | | Alive | | |
| **Population (select one)** | | Only my patients | | |
| | | Seen in my department | | |
| | | All patients who meet the criteria | | |
| | | Other | | |
| **Age (eg ≥18)** | | >          < | | |
| | | | | |
| **Diagnosis/ Clinical Findings (select ≥ 1) "or" criteria** | ✓ | **Description** | **Code Set** | **Code[11,12]** |
| | | chronic myeloid leukemia, BCR::ABL positive | ICD-10 | C92.10 |
| | | chronic myeloid leukemia, BCR::ABL positive, in remission | ICD-10 | C92.11 |
| | | chronic myeloid leukemia, BCR::ABL positive, in relapse | ICD-10 | C92.12 |
| | | chronic myeloid leukemia, disease; disorder | SNOMED | 92818009 |
| | | myeloid leukemia in relapse; disorder | SNOMED | 122901000119109 |
| | | relapsing chronic myeloid leukemia; disorder | SNOMED | 415287001 |
| | | chronic myeloid leukemia category; morphologic abnormality | SNOMED | 413841000 |
| | | chronic phase chronic myeloid leukemia; disorder | SNOMED | 413847001 |
| **Medications (to identify patients who have lapsed TKI therapies and may be struggling with side effects) "or" criteria** **Note: Insert FDA approved TKIs (or other medications) here.** | ✓ | **Description** | **Code Set** | **Code** |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | Patients who have TKI medications that have lapsed (eg, 30-day prescription + 2 refills = 90 days supply, current date is >90 days from the original prescription, and not renewed with additional refills) | Lookback period: (starting today) or Date range:          - | |

(left vertical label) **INCLUSION CRITERIA**

# Noncompliant Patient (continued)

## Exclusion Criteria for Patient Report and BPA

| CATEGORY | ✔ | VALUES | | |
|---|---|---|---|---|
| | ✔ | Description | Code Set | Code |
| Health system to add exclusion criteria if desired | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

EXCLUSION CRITERIA

## Noncompliant Patient (continued)

### Report Output Columns

| CATEGORY | ✔ | VALUES | | |
|---|---|---|---|---|
| **Patient Demographics** | | Patient ID (MRN) | | |
| | | Name | | |
| | | DOB | | |
| | | Phone Number | | |
| | | MyChart Status | | |
| **Diagnosis/ Clinical Findings** | ✔ | **Description** | **Code Set** | **Code[11,12]** |
| | | chronic myeloid leukemia, BCR::ABL positive | ICD-10 | C92.10 |
| | | chronic myeloid leukemia, BCR::ABL positive, in remission | ICD-10 | C92.11 |
| | | chronic myeloid leukemia, BCR::ABL positive, in relapse | ICD-10 | C92.12 |
| | | chronic myeloid leukemia, disease; disorder | SNOMED | 92818009 |
| | | myeloid leukemia in relapse; disorder | SNOMED | 122901000119109 |
| | | relapsing chronic myeloid leukemia; disorder | SNOMED | 415287001 |
| | | chronic myeloid leukemia category; morphologic abnormality | SNOMED | 413841000 |
| | | chronic phase chronic myeloid leukemia; disorder | SNOMED | 413847001 |
| **Payer** | | Insurance Coverage Name | | |
| **Last Documented BCR::ABL** | | LOINC Code | | |
| | | Description | | |
| | | Value | | |
| | | Date | | |
| **TKI Prescription Activity** | | Active TKI Medication Name | | |
| | | Date Prescribed | | |
| | | End Date | | |
| | | Previous TKI Medication Name | | |
| | | Date Prescribed | | |
| | | End Date | | |
| **Care Team Member** | | Care Team Member Name | | |
| **Additional Clinical Criteria** | | | | |

REPORT OUTPUT COLUMNS

# Non compliant Patient (continued)

## BPA Content

| | CATEGORY | ✔ | VALUES |
|---|---|---|---|
| **BPA CONTENT** | **BPA Name (eg, Patients who are non-compliant.)** | | |
| | **Message to include in BPA (eg, "This patient with CML has TKI medications that have lapsed.")** | | |
| | **Data to include in BPA** | | Current TKI Prescription |
| | | | Date TKI Prescribed |
| | | | Additional Clinical Criteria |
| | **Clinical actions to take based on the BPA** | | CML Order Set Name                              # |
| | | | Order BCR::ABL lab test |
| | | | Order Appropriate Medication |
| | | | Add Diagnosis C92.10 |
| | | | Additional Orderable Items to Include |

# Patient Not Meeting Milestones

Before you begin to build on this topic, it's important to consider several key technical questions that will influence the impact of your BCR::ABL program.

## Technical Considerations:

Are results interfaced back to your EHR?

| OPTION | ACTIONS |
|---|---|
| **Yes** – our results interface returns BCR::ABL results and completes the original order | Proceed with EHR report and BPA build |
| **No** – we don't receive results digitally to our EHR | Do not proceed with build – pursue an interfaced result option with your interfaces team before moving forward |

If yes above, are interfaced results filed to discrete result values in your EHR?

| OPTION | ACTIONS |
|---|---|
| **Yes** – results file to discrete components in the patients chart in a usable data format | Proceed with EHR report and BPA build |
| **No** – results file as a PDF/image to the chart in a generic, non-reportable format | Proceed with EHR report and BPA build but note operational impact below |

## Operational Impact:

If you are not receiving discrete results for your BCR::ABL tests, the build is still possible but there is a greater operational burden placed upon the program.

Reports that are built to identify patients with missing or overdue results will return patients who have had the order completed but the EHR won't be able to return that data. This places the onus of follow-up onto whoever is managing the reports and the population. In other words, operational owners running these reports will need to do manual follow-up in the chart or with the patient directly to determine if the result was completed and then manually key those results into the patients chart.

Given the relatively small size of the population who would be doing this testing, this may not be a significant lift and may be worth it for your organization. However, it's important to plan for the additional workload.

# Patient Not Meeting Milestones

## Inclusion Criteria for Patient Report and BPA

<table>
<tr>
<th></th>
<th>CATEGORY ("AND" CRITERIA)</th>
<th>✓</th>
<th colspan="4">VALUES</th>
</tr>
<tr>
<td rowspan="20">INCLUSION CRITERIA</td>
<td>Patient Status</td>
<td></td>
<td colspan="4">Alive</td>
</tr>
<tr>
<td rowspan="4">Population (select one)</td>
<td></td>
<td colspan="4">Only my patients</td>
</tr>
<tr>
<td></td>
<td colspan="4">Seen in my department</td>
</tr>
<tr>
<td></td>
<td colspan="4">All patients who meet the criteria</td>
</tr>
<tr>
<td></td>
<td colspan="4">Other</td>
</tr>
<tr>
<td>Age (eg ≥18)</td>
<td></td>
<td colspan="4">&gt;          &lt;</td>
</tr>
<tr>
<td></td>
<td></td>
<td colspan="4"></td>
</tr>
<tr>
<td rowspan="9">Diagnosis/ Clinical Findings (select ≥ 1) "or" criteria</td>
<td>✓</td>
<td>Description</td>
<td>Code Set</td>
<td>Code[11,12]</td>
</tr>
<tr>
<td></td>
<td>chronic myeloid leukemia, BCR::ABL positive</td>
<td>ICD-10</td>
<td>C92.10</td>
</tr>
<tr>
<td></td>
<td>chronic myeloid leukemia, BCR::ABL positive, in remission</td>
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<td>C92.11</td>
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<td>chronic myeloid leukemia, BCR::ABL positive, in relapse</td>
<td>ICD-10</td>
<td>C92.12</td>
</tr>
<tr>
<td></td>
<td>chronic myeloid leukemia, disease; disorder</td>
<td>SNOMED</td>
<td>92818009</td>
</tr>
<tr>
<td></td>
<td>myeloid leukemia in relapse; disorder</td>
<td>SNOMED</td>
<td>122901000119109</td>
</tr>
<tr>
<td></td>
<td>relapsing chronic myeloid leukemia; disorder</td>
<td>SNOMED</td>
<td>415287001</td>
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<td>chronic myeloid leukemia category; morphologic abnormality</td>
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<tr>
<td></td>
<td>chronic phase chronic myeloid leukemia; disorder</td>
<td>SNOMED</td>
<td>413847001</td>
</tr>
</table>

# Patient Not Meeting Milestones (continued)

## Inclusion Criteria for Patient Report and BPA (continued)

| CATEGORY ("AND" CRITERIA) | ✔ | VALUES | | |
|---|---|---|---|---|
| **Lab Tests** | ✔ | **Description** | **Code Set** | **Code[13]** |
| | | BCR::ABL1 kinase domain targeted mutation analysis | LOINC | 55135-8 |
| | | | Local | |
| | | BCR::ABL Date Range<br>Date of BCR::ABL lab result<br>(eg, greater than 6 months is [>m-6]) | Lookback period:<br>(starting today)<br><br>or<br><br>Date range:                    - | |
| | | BCR::ABL Lab Value Range<br>Capturing out-of-range BCR::ABL lab test<br>(eg, >0.1%, 0.1% - 1%, >1%) | Value: >            < | |
| **Patients TKI activity** | ✔ | **# of Current and Previous TKI Therapies** | | |
| | | ≥ | | |

Left vertical label: **INCLUSION CRITERIA**

# Patient Not Meeting Milestones (continued)

## Exclusion Criteria for Patient Report and BPA

<table>
<tr><th rowspan="7">EXCLUSION CRITERIA</th><th>CATEGORY ("AND" CRITERIA)</th><th>✓</th><th colspan="4">VALUES</th></tr>
<tr><td rowspan="2">Exclude patients with TKI history (eg, &lt;2)</td><td>✓</td><td colspan="4"># of Current and Previous TKI Therapies</td></tr>
<tr><td></td><td colspan="4">&lt;</td></tr>
<tr><td rowspan="4">Exclude patients who have had a recent BCR::ABL ordered within 3 or 6 months</td><td>✓</td><td>Description</td><td>Code Set</td><td>Code[13]</td></tr>
<tr><td></td><td rowspan="2">BCR::ABL1 kinase domain targeted mutation analysis</td><td>LOINC</td><td>55135-8</td></tr>
<tr><td></td><td>Local</td><td></td></tr>
<tr><td></td><td>BCR::ABL Future Date Range<br>Timeframe for capturing BCR::ABL order<br>(eg, m-6)</td><td colspan="2">Lookback period: (starting today)<br><br>or<br><br>Date range:      -</td></tr>
</table>

# Patient Not Meeting Milestones (continued)

## Report Output Columns

| | CATEGORY | ✔ | VALUES | | |
|---|---|---|---|---|---|
| **REPORT OUTPUT COLUMNS** | **Patient Demographics** | | Patient ID (MRN) | | |
| | | | Name | | |
| | | | DOB | | |
| | | | Phone Number | | |
| | | | MyChart Status | | |
| | **Diagnosis/ Clinical Findings** | ✔ | **Description** | **Code Set** | **Code[11,12]** |
| | | | chronic myeloid leukemia, BCR::ABL positive | ICD-10 | C92.10 |
| | | | chronic myeloid leukemia, BCR::ABL positive, in remission | ICD-10 | C92.11 |
| | | | chronic myeloid leukemia, BCR::ABL positive, in relapse | ICD-10 | C92.12 |
| | | | chronic myeloid leukemia, disease; disorder | SNOMED | 92818009 |
| | | | myeloid leukemia in relapse; disorder | SNOMED | 122901000119109 |
| | | | relapsing chronic myeloid leukemia; disorder | SNOMED | 415287001 |
| | | | chronic myeloid leukemia category; morphologic abnormality | SNOMED | 413841000 |
| | | | chronic phase chronic myeloid leukemia; disorder | SNOMED | 413847001 |
| | **Payer** | | Insurance Coverage Name | | |
| | **All BCR::ABL lab results in last 24 months** | | LOINC Code | | |
| | | | Description | | |
| | | | Value | | |
| | | | Date | | |
| | **TKI Prescription Activity** | | Date Prescribed | | |
| | | | Name of TKI Prescribed | | |
| | **Additional Clinical Criteria** | | | | |

# Patient Not Meeting Milestones (continued)

## BPA Content

| | CATEGORY | ✔ | VALUES |
|---|---|---|---|
| **BPA CONTENT** | **BPA Name (eg, Patients who are resistant to TKI therapy.)** | | |
| | **Message to include in BPA (eg, "This patient with CML has outdated lab values or This patient has out-of-range lab values.")** | | |
| | **Data to include in BPA** | | Current TKI Prescription |
| | | | Date TKI Prescribed |
| | | | BCR::ABL LOINC code |
| | | | Description |
| | | | Value (list all values for last 24 months) |
| | | | Date (list all dates for last 24 months) |
| | | | Additional Clinical Criteria |
| | **Display Restrictions** | | Care team member |
| | | | Other |
| | **Clinical actions to take based on the BPA** | | CML Order Set Name                                    # |
| | | | Order BCR::ABL lab test |
| | | | Order Appropriate Medication |
| | | | Add Diagnosis C92.10 |
| | | | Additional Orderable Items to Include |

# Establishing a Flowsheet

## Documenting TKI Side Effects

Identifying a TKI-intolerant patient is supported by the gathering of discrete side effect data. Early screening and tracking of those side effects in the EHR are important for patient care.

One method of side effect tracking is to create a document Flowsheet with a filter and then use a Smartlink to pull the data into a note.

### Create the Rule

- In the Rule Editor, create a new rule using Patient context, and name the rule, for example Filter for Ph+CML-CP Diagnoses. Select Accept

- In the rule Activity, enter detailed description

- From the Properties tab, expand the Patient tree, then search for the 49023 - Primary Diagnosis property

- Enter the diagnosis or diagnosis grouper and set the Operator to = (equals); select Accept

### Create the Template

- In the Doc Flowsheet Builder, create a General Flowsheet Template

- Use a descriptive Display Name and a Tab Name, such as TKI Related Side Effect Rating

- In the Filter Rule field, enter the rule created above (e.g., Filter for Ph+CML-CP Diagnoses)

- Build rows based on the side effect questions, using a value of Custom Formula; one side effect per row

- Using a Custom Formula enables the practice to determine intensity levels for the side effect range, for example 1-5, mild to severe



*Hypothetical example of a Flowsheet with TKI side effects*

**References: 1.** Goldberg SL. Monitoring chronic myeloid leukemia in the real world: gaps and opportunities. *Clin Lymphoma Myeloma Leuk*. 2015;15(12):711-714. **2.** Milojkovic D, Apperley J, Gerrard G, et al. Responses to second-line tyrosine kinase inhibitors are durable: an intention-to-treat analysis in chronic myeloid leukemia patients. *Blood* 2012;119(8):1838–1843. **3.** Jabbour E, Parikh SA, Kantarjian H, et al. Chronic myeloid leukemia: mechanisms of resistance and treatment. *Hematol Oncol Clin North Am*. 2011;25(5):981-995 **4.** Patel AB, O'Hare T, Deininger MW. Mechanisms of resistance to ABL kinase inhibition in chronic myeloid leukemia and the development of next generation ABL kinase inhibitors. *Hematol Oncol Clin North Am*. 2017;31(4):589-612. **5.** Deangelo DJ. Managing chronic myeloid leukemia patients intolerant to tyrosine kinase inhibitor therapy. *Blood Cancer J*. 2012;19;2(10):e95. **6.** Hochhaus A, Saglio G, Hughes TP, et al. Long-term benefits and risks of frontline nilotinib vs imatinib for chronic myeloid leukemia in chronic phase: 5-year update of the randomized ENESTnd trial. *Leukemia*. 2016;30(5):1044-1054. **7.** Noens L, van Lierde MA, De Bock R, et al. Prevalence, determinants, and outcomes of nonadherence to imatinib therapy in patients with chronic myeloid leukemia: the ADAGIO study. *Blood*. 2009;113(22):5401-5411. **8.** Boons CCLM, Timmers L, Janssen JJWM, et al. Response and adherence to nilotinib in daily practice (RAND study): an in-depth observational study of chronic myeloid leukemia patients treated with nilotinib. *Eur J Clin Pharmacol*. 2020;76(9):1213-1226. **9.** Ibrahim AR, Eliasson L, Apperley JF, et al. Poor adherence is the main reason for loss of CCyR and imatinib failure for chronic myeloid leukemia patients on long-term therapy. *Blood*. 2011;117(14):3733-3736. **10.** Chen TC, Chen LC, Huang YB, Chang CS. Imatinib adherence associated clinical outcomes of chronic myeloid leukaemia treatment in Taiwan. *Int J Clin Pharm*. 2014;36(1):172-181. **11.** Medical billing codes search. Codify by AAPC. Accessed February 1, 2024. https://www.aapc.com/codes/code-search/ **12.** Health terminology code search. SNOMED CT Browser: National Library of Medicine. Accessed February 1, 2024. https://browser.ihtsdotools.org/? **13.** Clinical observation codes search. SearchLOINC: LOINC Regenstrief Institute, Inc. Accessed February 1, 2024. https://loinc.org/search/

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