We thank all centers and patients for participating in this survey!

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INTRODUCTION
Primary care for patients (patients) with chronic myeloid leukemia (CML) in Germany is mainly provided by decentralized oncology practices. In contrast, clinical trials for new substances are usually carried out in specialized centers and university clinics, resulting in a lack of data on current treatment practice outside these centers.

OBJECTIVE(S)
The aim of this study was to assess clinical routine treatment practice in patients with CML in real-world setting of private oncology practices in Germany.

METHOD(S)
Patients with a confirmed diagnosis of CML in 2013 or later were eligible for inclusion. European Leukemia Net (ELN) recommendations for CML 2013 definitions were used for diagnosis and response assessment. Anonymized and aggregated data per site was used.

RESULT(S)
A total of 819 patients (mean age 58.5 years, range 15-91) were reviewed (figure 1.2.3). CML specific risk scores at diagnosis were available for 343 (41.8%). EUtos score in 86.0% of these patients (table 1). 61.9% (n=503) patients had data available on spleen size and the calculated European long-term survival scores (ELTS) were low, intermediate, high in 53.0, 32.2 and 14.9% of patients, respectively. At diagnosis, 84.2% (n=690) and 9.4% (n=77) patients were in chronic or accelerated phase, 0.7% (n=6) had a blast crisis and data was missing in 5.6% (n=46) patients.

Molecular Monitoring was provided EUtos certified laboratories for 87.7% (n=718). A typical BCR-ABL1 transcript was detected in 86.6% (n=709). Cytogenetics at diagnosis were obtained in 71.2% (n=588) of patients. Mean time from initial diagnosis to treatment was 1.2 months (m, range 0-92m). Molecular response was assessed after 2.8, 6.0, 9.4 and 12.9 m (mean) after start of treatment. 11.1% (69/633) of patients with available qPCR data did not achieve early molecular response (BCR-ABL1 IS ≤10% at 3 months, figure 4). At 18 m, 83.7% (328/392) of patients with available PCR data had at least a major molecular response. Treatment had been changed to 2L in 41.5% (n=340) of patients (288: 2nd TKI, 2: HEVI, SI: off treatment) after a mean of 21.0 m (figure 1, 8). 56 patients had a modification of the ABX-kinase domain at the time of treatment change (figure 5). The most common reason for 2L treatment were side effects (43.4%), followed by insufficient response (31.4%), suboptimal response or failure according to ELN 2013, figure 6). Of the 288 patients switching to 2L treatment, 106 went on to 3L treatment (after a mean of 17.6 m, range 0-97 m) and 17 patients did not receive further treatment 2 patients entered a clinical trial (figure 1). Molecular response assessments in 2L were done after 2.3, 5.3, 8.3, and 11.7 m (mean), 31.1% (n=33/106) of all patients switched to 4L treatment and 92.8% (n=92/92) of patients still on 3L treatment achieved BCR-ABL1 IS ≤1% at 12 m (figure 7). 6 patients discontinued 3L and treatment was switched (HEVI-TKI, 23) after a mean time of 14.5 m (range 0.1-80.5 m, figure 8). Reasons for change were side effects in 42.4%, insufficient response in 33.3%, and other reasons in 24.2% of patients. 8 patients were referred to a specialized center.

CONCLUSIONS
Patients with CML in Germany are mainly treated in private practices. CML specific risk scores are calculated at diagnosis in only about 60% of patients, whereas cytogenetic analysis at initial diagnosis and molecular monitoring in a EUtos certified lab were performed in most patients. About 1/3 of all patients received hydroxyurea pre-treatment before initiation of 1st line therapy. Regardless of good molecular responses, 35.2% of patients received a 2L treatment, mainly due to adverse events. In contrast to ELN recommendations, cytogenetic or mutational analysis was performed only in a minority of patients with treatment failure.

Table 1: Patient Characteristics

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Number of patients</th>
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<tbody>
<tr>
<td>Sex (M/F)</td>
<td>female 399 (48.6%) / male 422 (51.4%)</td>
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<tr>
<td>Age at diagnosis (range)</td>
<td>18.5 (15-91)</td>
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<tr>
<td>Spleen palpable at diagnosis (%)</td>
<td>yes 501 (61.7) / not palpable 318 (38.3)</td>
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<tr>
<td>Risk score at diagnosis (n=588) (N=612)</td>
<td>chronic 309 (50.6%) / intermediate 150 (24.6%) / high 153 (24.8%)</td>
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<tr>
<td>Calculated scores by investigators (n=612)</td>
<td>EUtos 154 (25.0%) / high 99 (16.3%) / missing 269 (43.9%)</td>
</tr>
<tr>
<td>CN2013 disease phase (n=588) (N=612)</td>
<td>chronic phase 360 (58.6%) / accelerated phase 77 (12.6%) / blast crisis 80 (12.6%) / missing 75 (12.1%)</td>
</tr>
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</table>

Figure 1: Overview of patient distribution

Figure 2: Total number of CML patients treated and number of documented patients in the participating centers

Figure 3: Patients by center and treatment line

Figure 4: Molecular response to 1st&2nd line treatment (non-missing data)

Figure 5: ABL-1 Kinase domain mutation analysis

Figure 6: Reasons for switching treatment by line

Figure 7: Molecular response to 3rd line & later treatment

Figure 8: Mean time to treatment change

ACKNOWLEDGEMENTS & CONTACT INFORMATION
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