CMREGISTRY: AN OBSERVATIONAL, MULTI CENTER, PROSPECTIVE FOLLOW-UP REGISTRY OF PATIENTS WITH CHRONIC PHASE CML WITH A HIGH PROBABILITY OF OBTAINING A STABLE DEEP MOLECULAR RESPONSE >CMR4 (IS).

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Background
Since the advent of Tyrosine Kinase Inhibitors (TKI), many patients diagnosed with Chronic Myeloid Leukemia (CML) in chronic phase could achieve a deep molecular response, defined as at least a 4-log reduction in the bcr-abl transcripts when measured by a standardized PCR on the International Scale (IS). These patients are expected to maintain their molecular response even after discontinuation of their TKI treatment. Several on-going clinical trials are exploring the best way of stopping TKI therapy and evaluating the patient and disease characteristics that could predict long term disease control without treatment.

Aims
The aim of CMRegistry is to collect clinical data and molecular information in the international scale for CML patients in Spain that have achieved a series of cytogenetic or molecular responses at different time points to any of the tyrosine kinase inhibitors currently available in Spain in order to monitor their progress and the achievement of a stable deep molecular response >$MR^{4\,(IS)}$. These data may be used to identify patients that would be candidates for inclusion in future discontinuation studies or combination studies with other compounds

Methods
This is an observational, multi-center, prospective study open to all CML patients that are receiving treatment with any of the tyrosine kinase inhibitors currently available in Spain and are likely to achieve (or have already achieved) a deep molecular response (>$MR^{4\,(IS)}$). This likelihood of achieving >MR^4 is defined for the purposes of the study as a bcr-abl/abl ratio of: 1) ≤ 1% at 3 months from start of TKI therapy; 2) ≤ 0.1% at 6 months from start of TKI therapy; or 3) ≤ 0.01% any time point during treatment. Clinical data have been collected using a specific CRF created exclusively for this study. All data were registered in an anonymous manner. The BCR-ABL ratios in the IS have been provided by standardized labs in Spain.

Results
From June 2014 to January 2016 a total of 732 patients were registered in the study. Median age was 55 years (18 – 78) and 440 patients were male. The Sokal risk groups were as follows: 254 patients low risk, 230 intermediate risk and 97 high risk. Hasford (Euro) risk stratification showed 223 patients low risk, 225 intermediate and 136 high risk. Eutos classification yielded 341 patients in the low risk and 220 in the high risk categories. The majority of patients received treatment with Imatinib (409 patients), Dasatinib (82 patients) or Nilotinib (122 patients). Of note, 5 patients received Bosutinib, 1 patient Ponatinib and 4 patients were treated with Interferon.So far 722 patients remain alive. 10 patients have died, mostly of non-CML related conditions such as Carcinoma (3 patients), Cerebral Hemorrhage, Ischemic heart disease, respiratory failure and sepsis (1 patient each). Interestingly, 2 patients developed progression of their CML to Accelerated phase and blast crisis (1 patient each).At present, 104 patients (14%) have achieved a MR^4 and 70 (10%) patients a MR^5, while 176 patients (24%) have obtained a complete molecular remission (undetectable bcr-abl transcripts with a sensitivity of at least 10^{-5}).

Conclusion
In summary, a large number of CML patients have been identified in Spain in a prospective study as having a promising molecular response that would predict for a sustained deep molecular remission. A significant proportion of these patients has already achieved a complete molecular remission and would be potential candidates for discontinuation studies.

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