HEMATO CE PROVES ITS EFFECTIVENESS

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THE STUDY SITES

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2. Institut für Hämatopathologie Hamburg, Germany;
3. Result Laboratorium, Netherlands;
4. Zentrum für Labormedizin St. Gallen, Switzerland (Principal Investigator: Dr. Justus Bürgi, Diagnostician: Dr. Abd Alrazzak Attar).

SUCCESSFUL

Clinical study

INTRODUCTION

It is estimated that about one in 75 men and one in 99 women will develop a leukemia during their lifetime, with both the incidence and prevalence of leukemic disorders being expected to rise as humanity's average life expectancy increases.[1]

This notion alone signifies the importance of proper - fast, accurate, and economically reasonable - diagnostic methods as one of the many cornerstones of modern leukemia management strategy.

Aware of the epidemiological need, the problems of increasing clinical pressure, and the laboratory personnel deficit, the hema.to team is dedicated to achieving resolution of these issues through development of a revolutionary tool to support diagnosing hematological malignancies.

Here we demonstrate results of our most recent clinical trial, give an overview of experimental methods used, and discuss the importance of our findings as well as our future perspectives.

"A revolutionary tool for diagnosing haematological malignancies"

STUDY CONTEXT, OUR PARTNERS AND OUR FINDINGS

In April and May 2022, a clinical trial has been conducted by the hema.to team and four of our highly recognised laboratory partners from three different European countries (listed on the previous page).

The trial´s objective consisted in an assessment of our tool´s ability to:

- consistently recommend a diagnosis at a level of accuracy equal or superior to a user-specified standard;
- consistently recommend a diagnosis with speed equal or superior to a human diagnostician's manual analysis speed;
- allow the user to easily verify or exclude the presence of a malignancy through 1.comparison of a given case with similar or different cases from other patient cohorts *and* 2. through analysis of a given patient´s levels of pathognomonic biomarker expression.

Our experiment has produced the following results:

HEMA.TO vs Legacy software

+7.5 % in sensitivity

+9.8 % in specificity

2.2 x higher diagnostic speed

Our findings indicate that hema.to is comparable or even superior to a human diagnostician in terms of accuracy and sensitivity - and all this at twice the diagnostician´s speed.

EXPERIMENT PROCEDURE & METHODS

A total of 192 patient cases with verified - *ground truth* - diagnoses have been selected using a supervised random procedure and assigned to one of the two arms of the study - the control (manual) or the test (hema.to-assisted) arm, with the total of 96 cases per arm.

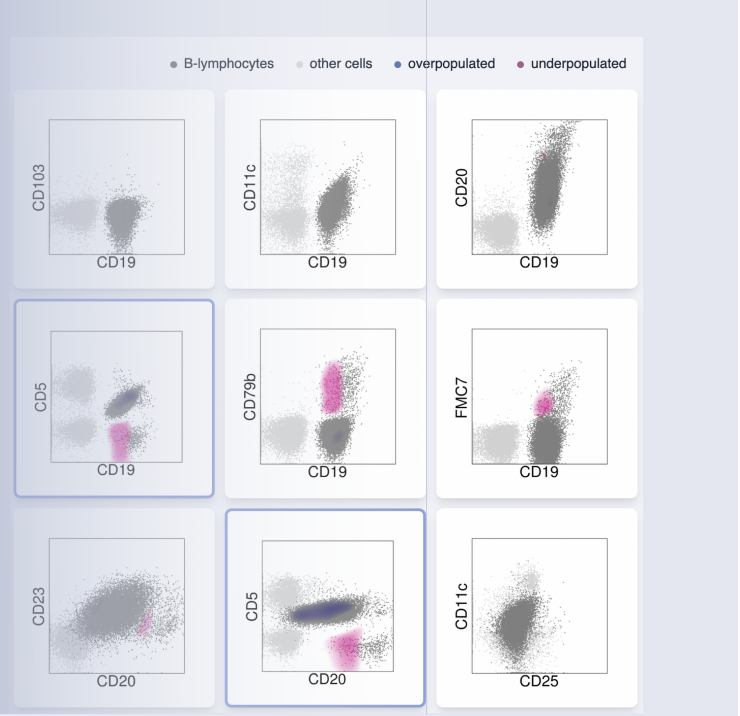
Furthermore, a scoring system has been established to calculate metrics and compare performance. Additionally, time to diagnosis has been measured for both study arms and compared.

Each of the four partner laboratories (or "sites"), acting independently of each other, have been tasked with diagnosing 24 cases from both the control and the test arms (2x24 cases, 48 cases per site in total), with their performance recorded by a blinded observer.

Subsequently, the diagnoses from both study arms have been compared to the ground truth diagnoses. Additionally, scores have been determined for each diagnostic method depending on the accuracy of the diagnoses obtained through either manual diagnostics or hema.to-assisted diagnostics. The final step was to ensure our calculations' correctness - to prove it, we applied a Welch's t-test with an a priori-defined p-value of 0.05 to metrics computed for both study arms.

hema.to supports all diagnosticians, regardless of their experience

tested cohort: 2 to 25 years of working experience



"The explicit visualisation of overpopulated and underpopulated regions, combined with the classic cytograms, directly points me to the correct diagnosis — this is just very, very good."

Dr. Richard Schabath,
Helios Klinikum Berlin-Buch

DISCUSSION OF FINDINGS AND FUTURE PERSPECTIVES

During analysis of our findings, we also compared scores obtained in the testing arm to the control arm to estimate an objectivity ratio.

Our calculations have produced the following results:

HEMA.TO vs Legacy software

+15% in objectivity

Diagnoses obtained with the help of hema.to were found to be in better agreement with the ground truth when compared to diagnoses obtained using a purely manual approach.

Our findings indicate that hema.to is fully capable of efficiently assisting diagnostic professionals, providing them with superior predictive power and greatly expanding their ability to correctly diagnose at least double the amount of cases in a given amount of time without sacrificing clinical accuracy.

We have thus managed to demonstrate exactly how our technology would benefit our customers - by enabling them to adequately manage high workloads even with limited personnel available by employing methods of innovative precision medicine.

The hema.to team is currently focused on integrating into the workflow of haematological laboratories - providing persistent support.

REFERENCES

1.RKI – Cancer in Germany 2017/2018; chapter 3.31 Leukaemia, p.142-145