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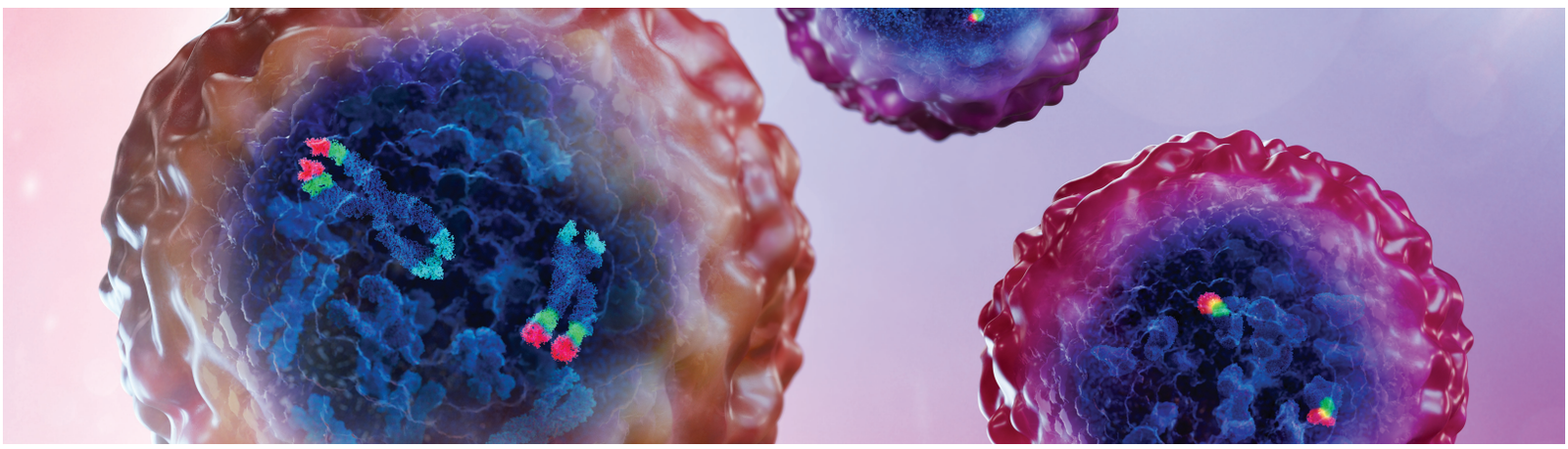
LIFE SCIENCE CASE REPORT | May 2024



CytoCell® IVD FISH probes for acute lymphoblastic leukaemia diagnosis

ALLTogether1 – A treatment study protocol of the ALLTogether Consortium for children and young adults (0-45 years of age) with newly diagnosed acute lymphoblastic leukaemia (ALL) – Laboratory Study Protocol Guidelines

EU Clinical Trials Register EudraCT number 2018-001795-38
Chief investigator: MD PhD Mats Marshall Heyman, Karolinska University Hospital, Sweden

Introduction

The primary objective of ALLTogether1 is to improve survival and quality of life in children and young adults with ALL. A sub-group of patients that may benefit from novel immunotherapy will be identified. The recruitment started in 2021 and will continue until at least May 2027.

The main treatment for ALL is chemotherapy, with a variety of drugs prescribed in different combinations. Chemotherapy usually works well for children and young adults with ALL. However, a better patient risk stratification would improve treatment plans and oncological outcomes, meaning less chemotherapy and reduced toxicity to patients in the low-risk group. The trial uses a combination of several factors to stratify patients into risk groups, determining the treatment they shall receive. This process includes investigating the gene abnormalities in leukaemic cells.

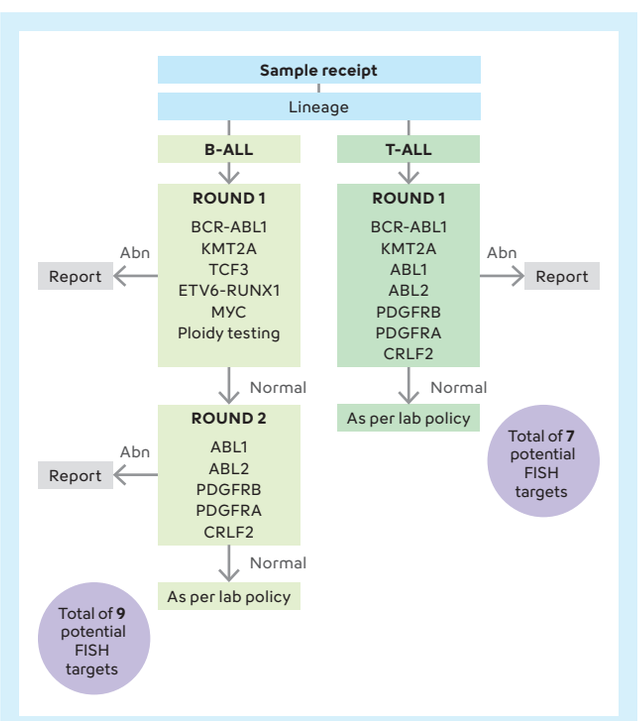


Fig. 1 Acute lymphoblastic leukaemia FISH test algorithm.

Table 1 CytoCell® IVD products that support the ALLTogether1 genetic risk stratification algorithm protocol implementation:

Cat. No.	Product name	Label	Status
LPH 031	PDGFRB Breakapart Probe		IVDD
CE-LPH 007	BCR/ABL (ABL1) Translocation, Dual Fusion Probe		IVDR
LPH 012	TEL/AML1 (ETV6/RUNX1) Translocation, Dual Fusion Probe		IVDD
CE-LPH 013	MLL (KMT2A) Breakapart Probe		IVDR
LPH 080	E2A (TCF3)/PBX1 *Plus* Translocation, Dual Fusion Probe		IVDD

Table 2 Other CytoCell myProbes® custom FISH probes that may aid in ALL research.

Cat. No.	Product name	Label	Status
MPH51700	PDGFRB/CSF1R Breakapart Probe		RUO
MPH51680	ABL2 Breakapart/TP53 Deletion Probe		RUO
MPD2680	JAK2 Breakapart Probe		RUO
MPH22100	MLL/AFF1 Breakapart/Dual Fusion Probe		RUO
MPH51690	CRLF2/P2RY8/IGH *Plus* Deletion/Breakapart Probe		RUO

'The availability of the CytoCell® probes has been a key factor for us to be able to specifically follow the ALL diagnostic algorithm following the guidelines.'

Dr Eva Villamón
Cytogenetic and Molecular Biology, Haematology Department
Clinic University Hospital of Valencia, Valencia, Spain

Consult your Sysmex representative to inquire about other CytoCell® solutions for FISH workflow optimisation.

References

[1] Heyman M. (2018): ALLTogether1 – A Treatment study protocol of the ALLTogether Consortium for children and young adults (0-45 years of age) with newly diagnosed acute lymphoblastic leukaemia (ALL). Clinical trials for 2018-001795-38.

[2] Moorman A. *et al.* (2021): Summary of the recommendations from the ALLTogether Genetics group for the genetic screening of patients treated on the ALLTogether1 Protocol.

OGT's CytoCell® IVDR-certified range of fluorescence *in situ* hybridisation (FISH) probe kits are *in vitro* diagnostic (IVD) medical devices for the detection of prenatal trisomy 13 & 21 and acquired cancer-related chromosome alterations. They have been CE-marked under Regulation (EU) 2017/746 (IVDR) as Class C IVD medical devices for laboratory professional use only and are not intended for use as a standalone diagnostic or companion diagnostic. Refer to each individual FISH probe kit's Instructions for Use for their specific Intended Purpose, Indications, and Limitations.
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