

iBFM FLOW *twinning* program

ALL IC-BFM center:	Ljubljana/Slovenia
AIEOP-BFM partner:	Vienna
Start of co-operation:	September 2013
Training periods:	December 2013

Track records ALL-MRD day 15

Guidelines

- "Maturation" to release MRD day15 results for clinical application without further control by the partner lab is granted to a center according to defined criteria.
- "Maturation" to release MRD day15 results for clinical application is separate by lineage.
- "Maturation" shall be granted upon completion of a series of 25 different patient sample pairs (dx and day15 MRD) per lineage jointly assessed and provided that NO GROSS failures to identify and quantify day 15 MRD were recorded in the most recent half (i.e. 12 patients) of the series.
- Gross failures are defined as "recurrent (>2x) inadequacy of staining and analysis", "blast population missed", "gross *miss-gating*".
- Gross *miss-gating* is e.g. defined by ">= 5-fold discrepancy between trainee's and supervisor's MRD result".
- Simple differences at prognostic thresholds (e.g. 0.09% vs. 0.11%) are NOT regarded gross failures although leading to different stratification.
- Each gross failure necessitates further 3 day15 assessments (same lineage) without failure in order to grant "maturation".
- In case of uncertainty, partner labs will be open for consultation also after granting "maturation".
- Traceability (i.e. n of cases, dates of analysis, n of failures...etc) of "maturation" has to be reported in an official track record form provided by the iBFM coordinator. The track record form is kept and completed at the AIEOP-BFM site based in parts on information provided by the ALL-IC center.
- "Maturation" accreditation must be communicated to and approved by the iBFM co-ordinator upon consensual suggestion by the twinning partners. Once consensus was found regarding "maturation", twinning partners should send the completed track record form to the iBFM FLOW co-ordinator. This can be accomplished at different time-points per lineage.
- The iBFM FLOW co-ordinator informs the ALL IC-BFM FLOW co-ordinator of granting "maturation" to an ALL IC-BFM FLOW center.

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Track record ALL-MRD day 15

B-lineage

(¹=ALL-IC center, ²=AIEOP-BFM partner)

	patient code¹	sampling date¹	date of review²	failure² Y/N	comment (failure type)
		/			
1	LJU-B-001	1.7.13/23.1.14	23.01.14	n	Some support needed
2	LJU-B-002	11.7.13/23.1.14	23.01.14	y	Risk not clear as 0,1%
3	LJU-B-003	31.01.14	4.2.14	n	negative
4	LKU-B-004	27.01.14	27.01.14	n	FHR
5	LJU-B-005	24.04.14	24.04.14	n	+d33
6	LJU-B-006	30.04.14/06.05.	07.05.14	n	o.k.
7	LJU-B-007	08.07.14	09.07.14	n	Normogate false; compensation
8	LJU-B-008		4.8.14	n	
9	LJU-B-009	30.10.14	4.11.14	n	fine
10	LJU-B-0010	30.10.14	4.11.14	n	fine
11	LJU-B-0011	26.11.14	11.12.14	n	fine
12	LJU-B-0012a	10.12.14	11.12.14	n	Fine/two pop
13	LJU-B-013	11.12.14	12.12.14	n	fine
14	LJU-B-014	25.01.15	27.01.15	n	Fine/but low
15	LJU-B-015	19.02.15	20.02.15	n	negative
16	LJU-B-016	20.03.15	20.03.15	n	o.k.
17	LJU-B-017	31.03.15	31.03.15	n	o.k.
18	LJU-B-018	09.04.15	09.04.15	n	o.k.
19	LJU-B-019	10.04.15	10.04.15	n	o.k.
20	LJU-B-020	01.05.15	01.05.15	n	o.k.
21	LJU-B-021	17.08.15	17.08.15	n	o.k.
22	LJU-B-022	07.09.15	07.09.15	n	Two blastpopulations
23	LJU-B-023	28.09.15	28.09.15	n	o.k.
24	LJU-B-024	3.11.15	3.11.15	n	o.k.
25	LJU-B-025	9.12.2015	9.12.15	n	First tube in 9-color combination
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failure types: 1) >2 samples with poor quality staining, 2) blast population missed,
3) gross miss-gating (e.g. ≥5-fold discrepant MRD value from reviewer)

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ALL IC-BFM center:	Ljubljana, Slovenia
AIEOP-BFM partner:	Vienna
Start of co-operation:	September 2013
Training periods:	December 2013
Maturation criteria fulfilled for B-Lin. ALL	YES Date: 10th December, 2015
Maturation criteria fulfilled for T-Lin. ALL	

* to be filled by AIEOP-BFM partner

“Maturation” granted for B-lineage ALL

AIEOP-BFM supervisor*: A. Schumich

date: _09.12.2015 _____

iBFM FLOW network coordinator: M. N. Dworzak

date: _10.12.2015 _____

*to be signed by representative of the AIEOP-BFM partner center