

Data Timeliness for site staff

June 2018

Data Timeliness

- The Data Timeliness (DTL) process describes how EORTC Headquarters centrally monitors site compliance related to Case Report Forms and Serious Adverse Events data submission.

Standard Timeframes and Color Codes

	PRESENT	DUE	OVERDUE	NA
Baseline forms	Present in EORTC database	< 3 months after registration	>= 3 months after registration	Not applicable
Treatment forms	Present in EORTC database	< 4 months after theoretical date	>= 4 months after theoretical date	Not applicable
Follow-up forms	Present in EORTC database	< 12 months after theoretical date	>= 12 months after theoretical date	Not applicable

Overdue forms should be provided in priority, followed by due forms

Theoretical date= expected date of form submission according to protocol

Overdue SAE queries

- **Overdue SAE queries** are Queries concerning Serious Adverse events where 3 reminders were sent

DTL Overview

Table showing per patient & treatment period present, due & overdue CRFs

This table is sent to EORTC investigators at each DTL time point, together with the listing of overdue SAE queries

Patient						randomizati on	onstudy	questionnair e	Patho	EGFR	onstudy		
SeqID	Inst	Present	Due	Overdue	Bugs	crg1	OS	Quest1	OS	OS	Blo1	Blo2	Plas
##	####	10	1	0	3	08/08/2014	17/06/2014	28/08/2014	08/08/2014	08/08/2014	08/08/2014	08/08/2014	08/08/2014
##	####	10	1	0	3	08/08/2014	21/03/2013	26/08/2014	08/08/2014	08/08/2014	08/08/2014	08/08/2014	08/08/2014
##	####	9	0	0	3	15/08/2014	16/05/2013	02/09/2014	18/08/2014	18/08/2014	18/08/2014	18/08/2014	18/08/2014
##	####	10	0	0	3	10/09/2014	31/05/2012	17/09/2014	10/09/2014	10/09/2014	10/09/2014	10/09/2014	10/09/2014
##	####	10	0	0	3	15/10/2014	11/03/2013	21/10/2014	15/10/2014	15/10/2014	15/10/2014	15/10/2014	15/10/2014
##	####	4	0	0	2	17/06/2015	22/05/2015		17/06/2015	17/06/2015			
##	####	5	1	0	2	05/08/2015	10/06/2015		05/08/2015	05/08/2015			
##	####	7	0	0	3	04/04/2016	03/02/2016	01/01/1900	06/04/2016	06/04/2016	06/05/2016	06/05/2016	06/05/2016
##	####	7	0	0	3	08/04/2016	11/12/2015	08/04/2016	08/04/2016	08/04/2016	08/04/2016	08/04/2016	08/04/2016
##	####	7	0	0	3	11/04/2016	25/03/2010	11/04/2016	11/04/2016	11/04/2016	11/04/2016	11/04/2016	11/04/2016
##	####	7	0	0	3	13/04/2016	25/03/2010	13/04/2016	13/04/2016	13/04/2016	13/04/2016	13/04/2016	13/04/2016
##	####	7	0	0	3	18/04/2016	04/11/2015	18/04/2016	18/04/2016	18/04/2016	18/04/2016	18/04/2016	18/04/2016
##	####	7	0	0	3	16/05/2016	18/11/2015	16/05/2016	16/05/2016	16/05/2016	16/05/2016	16/05/2016	16/05/2016
##	####	6	1	0	2	20/07/2016	14/10/2015	20/07/2016	03/08/2016	20/07/2016	20/07/2016	20/07/2016	20/07/2016

DTL time points



DTL process takes place 3 times a year, in February, June and October.

At these time points you will receive per trial and per institution:

- a DTL overview
- The pending overdue SAE queries

Alarm email

- An institution is considered to be in alarm when the DTL overview presents $\geq 10\%$ overdue forms and more than 10 overdue forms or when there are >3 overdue SAE queries
- The institution is given 4 months (until next DTL time point) to solve the situation
- If at next time point the situation did not improve, actions can be taken

Possible actions

- The clinical data manager and pharmacovigilance managers will contact you to help you entering missing data
- A site visit or training can be planned
- The investigator can be “DTL suspended”, meaning:
 - No more patients can be entered in his/her participating studies
 - He/she will not be approached for new studies participation

Until the situation is resolved

(return below 10% overdue forms and all overdue SAE queries answered)

How to avoid 'DTL suspension'?

- Regularly submit due and overdue forms
- Promptly reply to SAE queries
- Contact the study Clinical Data Manager and /or Pharmacovigilance manager in case of question or issue

Thank you