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Newsletters and presentation slides

ST-006-WIN-04

Version 3

ALWAYS REFER TO THE INTRANET TO CHECK THE VALIDITY OF THIS DOCUMENT

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1 PURPOSE

To describe the instructions for the preparation of the general and study-specific newsletter for EORTC studies and the presentation slides of the ongoing EORTC studies in the scope of the Disease/Treatment Oriented and Task Force Group meetings.

2 INSTRUCTION

2.1 General

A standard template is the most efficient way to generate consecutive and uniform communication on EORTC study stages and EORTC group activities. To maintain uniformity, templates are available for the general and study-specific newsletters and presentation slides.
To facilitate the workload planning of all involved departments, at least 3 months before the group meeting the general overview on group meetings page in SharePoint should be updated with the date of the upcoming group meeting and other relevant information for each study. The study Project Manager (PM) is responsible for listing their studies and notifying the study team in case the information was changed or needs an update.
To ensure respect of the timelines, the preparation of SAS programs for all new studies should follow ST-003-SOP-02.

2.2 Newsletters

Newsletters are organized in sections (see Table 1 and Table 2).
The inclusion of sections is decided by the study team (e.g. trial status, accrual numbers,…) and each section should contain only the core message.

2.2.1 Study-specific newsletter

2.2.1.1 Organization

The study-specific newsletter is applicable for all EORTC studies that are:

- In regulatory activation;
- Currently open to recruitment;
- Closed for recruitment within the last 6 months and for which a database lock is planned;
- Studies with database lock planned for final analysis in the coming 6 months.

The study-specific newsletter is only applicable if EORTC is the official Sponsor unless contractually agreed upon with the official Sponsor.

2.2.1.2 Preparation and Distribution

The Disease Oriented Group Project Manager (DOG PM) generates an email to the group team specifying the date of the group meeting and the studies requiring a study-specific newsletter.
The study PM initiates the study-specific newsletter using the EORTC study newsletter template at least 6 weeks before the group meeting and saves it on J/unit in the group specific folder of the group meeting.
The study PM notifies the team of the location of the newsletter template and informs them about the deadline for which the review should be final.

Sections	Regulatory in process	Recruiting	Closed for recruitment (in the last 6 months before Group meeting)
Study design	X	X	X
Announcements	X	X	X
Accrual		X[1]	X
Site activation	X	X	
Medical Review & Safety	*	X	X
Database Status		X	X
Contacts	X	X	X

Table 1: Content of study-specific newsletter
*: optional
1: accrual graph with prediction curve

The study PM provides the information needed to generate the accrual graph to the study Clinical Data Manager (CDM) in the EORTC site activation sheet for accrual graph. The CDM requests the accrual graph and the AE tables to the SAS CDMs (sasdm@eortc.be) using the template e-mail.
In parallel, the Clinical Data Experts designate for each group a responsible CDM that will request the SAE tables for all studies of the DOG via e-mail to the Pharmacovigilance Unit (PVU) (pharmacovigilance@eortc.be) with all concerned CDMs in cc.
When agreed as final by study team and Clinical Data Expert (CDE), the study PM sends the draft Newsletter to the Study Coordinator(s) for review.
Study coordinator(s) are given 5 working days to review the newsletter before submission to the Communication Office, but no formal approval is needed to proceed. If contractually agreed, Intergroup and Company could also participate in the review.
After the approval of the study team, the PM submits the newsletter as a hyperlink to the Communication Office (communication@eortc.be), for the creation of the test newsletter, stating the deadline of distribution in the template email.
Newsletters should be provided to the Communication Office at least 3 weeks before the meeting and are considered final. A delay can be accepted up to 2 weeks before the meeting for following exceptions:

- Studies in “Regulatory Activation” for which the date of first site activation can be reached near the meeting date;
- Studies in “Recruitment” for which the last patient in (LPI) can be reached near the meeting date;
- Studies “Closed for recruitment” within the last 6 months and for which the database lock is planned;
- Studies with planned database lock for final analysis in the coming 6 months.

The test newsletter is sent to the study PM for final proofreading and approval. In addition to the final approval, study PM provides the Communication Office the mailing list for distribution. The mailing list should include all actively involved site staff (e.g. principal investigators, sub-investigators, data managers, etc.), Intergroup (if applicable) and Company (if applicable).
The latest day of distribution is one day before the group meeting (see Figure 1).
Following distribution, the Communication Office provides a PDF version of the newsletter to the study PM for filing in the TMF and posting on the study documentation portal (StudyWebDocs).

2.2.2 General Group newsletter

2.2.2.1 Organization

The general Group newsletter includes all board-endorsed EORTC studies and high-profile research projects, which are:

- With outline or protocol in development;
- In regulatory activation;
- Currently open to recruitment;
- Closed for recruitment, but awaiting final analysis;
- In long-term follow-up.

2.2.2.2 Preparation and Distribution

The DOG PM initiates the general Group newsletter 3 weeks before the Group meeting by providing a first draft of the newsletter to the HQ team members and Group / Task Force Officers for review (5 working days). After approval by the HQ team members and Group / Task Force Officers (if applicable), the DOG PM submits the general Group newsletter to the Communication Office (communication@eortc.be) using the template email for the creation of the test newsletter at least 1 week before the Group meeting. The test newsletter is sent to the DOG PM for final proofreading and approval. In addition to the final approval, DOG PM provides the Communication Office the mailing list for distribution. The mailing list should include Group / Task Force officers, associate members and corresponding members. The latest day of distribution is one day before the group meeting (see Figure 1).
Following distribution, the Communication Office provides a PDF version of the newsletter to the DOG PM for filing in the TMF and posting on the Group / Task Force website.

Sections	General newsletter
Announcements	*
Studies	X
Recent publications	*
Save the date	X
Group contacts	X

Table 2: Content of general Group newsletter. *: optional

2.3 Presentation slides

Presentation slides are organized in sections (Table 3). The inclusion of the optional sections and content is decided by the study team. Compared to the newsletter, the presentation could contain additional information.

2.3.1 Organization

The study-specific presentation slides are mandatory for studies that will be presented during the group meeting and applicable for all studies that are:

- In regulatory activation;
- Currently open to recruitment;
- Closed for recruitment within the last 6 months and for which the database lock is planned;
- Studies for which the database lock for final analysis is planned in the coming 6 months.

2.3.2 Preparation and Distribution

The study CDM initiates the study-specific slides 3 weeks before the group meeting. A first draft is saved on J/unit in the group specific folder for group meeting and the link is sent to study team for review. After approval by study team (including CDE) and at latest 1 week before the group meeting, the slides are sent for information to the study coordinator(s). The accrual graph should be updated when new patients have been registered/enrolled in between. The slides will be updated with the latest numbers and should be final at the latest 2 days prior the presentation day (see Figure 1).

After the group meeting, the study CDM creates a PDF version of the presentation and files in the TMF and sends it to the study PM for upload on the study documentation portal (StudyWebDocs).

Sections	Regulatory in process	Recruiting	Closed of recruitment (in the last 6 months before Group meeting)
Title slide	X	X	X
Study design	X	X	X
Accrual		X[1]	X
Site activation	X	*	*
Population characteristics		*	*
Medical review & safety		*	*
Database Status		X	X
Announcements	X	*	*

Table 3: content of presentation slides depending on the study phase

*: optional

1: accrual graph with prediction curve

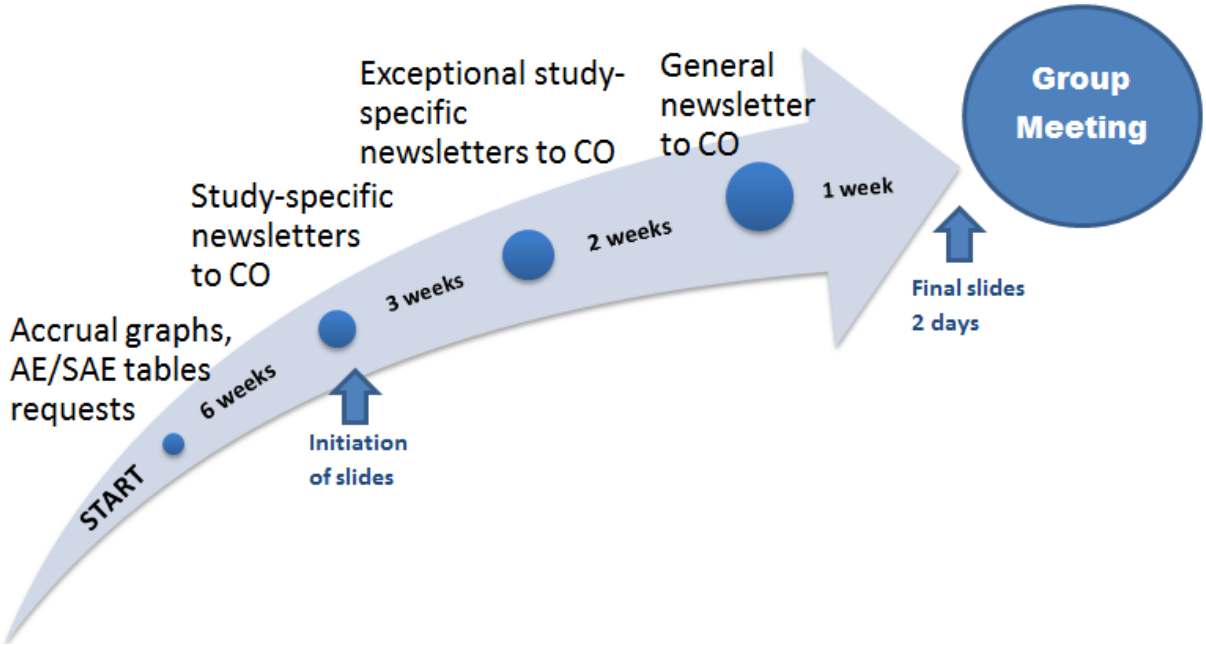

Figure 1: Summary of the timelines for the information requests and sending the newsletters to Communication Office.

CO: Communication Office

Note: the newsletters are sent to Communication Office only after approval of the study team and are considered final.

3 ASSOCIATED DOCUMENTS

Document title	Reference (file name or path)
General newsletter template	http://portal2016.eortc.be/db2/References/Quality_Standard_Documents/Templates/Forms/AllItems.aspx
Study-specific newsletter template	
Presentation slides template	
Site activation sheet for the accrual graph (Excel table)	
Accrual graph request (email template)	
Request to Communication Office (email template)	
Group meetings page with general overview per study	http://portal2016.eortc.be/db2/Projects/Group_Meetings/SitePages/Home.aspx

4 DOCUMENT HISTORY

Version N°	Brief description of change	Author	Effective date
1.0	Initial release, superseding information on TSR reported in WP1302 version 4.1	Bart Meulemans	14 Sep 2011
1.0	No change	Bart Meulemans	23 Sep 2014
2	TSRs become Newsletters. Implementation of standardized newsletter templates and presentation slides.	Yuliya Vostrikova	14 Sep 2017
3	Implementation of the Group meetings page with general overview per study to streamline the process	Yuliya Vostrikova	15 Dec 2017