# ENGOT Administrative meeting feedback

# ENGOT Admin Meeting

| Agenda |
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| 1. Introduction |
| 2. ENGOT Documentation Checklist |
| 3. Update of ADAMON Study and TEMPER Study |
| 4. ICON 6: monitoring set-up and audit |
| 5. Budgeting a trial |
| 6. Update on EU regulation and GCP amendment |
| 7. ENGOT monitoring network – resource sharing project |
| 8. AOB |

## 2. ENGOT documentation checklist (25 min) – R. Berger

ENGOT founded in 2007

« Progress in gynaecologic oncology needs clinical studies, translational research and cooperation… and a strong academic and independant structure «

Inventory and collection of all documents ever produced in the course of ENGOT

Prepared some new documents

E.g. checklists, handbooks, SOPs, Guidelines, Surveys, Publications, Brochure

# ENGOT Admin Meeting

## 2. ENGOT documentation checklist

| ENGOT SOPs, Guidelines | Document last version | Location | Status | Description |
|---|---|---|---|---|

**SOP Administration of new ENGOT trials and reporting - 2016**

**SOP ENGOT meetings management - 2016**

**ENGOT Bylaws - 2013**

**Guidelines for ENGOT minimals requirements for site selection - 2015**

**Guidelines for authorship - 2009**

**ENGOT Introduction/Welcome package - 2016** NEW

## 2. ENGOT documentation checklist

**Publications**

**Clinical trials brochure – 2015**

**European Network of Gynaecological Oncological Trial Groups' Requirements for Trials Between Academic Groups and Pharmaceutical Companies – First update 2015**

**The European Network for Gynaecological Oncological Trial Groups Charta for Privileged Partnership - 2015**

**Roadmap for the European Network of Gynaecological Trial groups (ENGOT) Trials - 2013**

**European Network of Gynaecological Oncological Trial Groups' Requirements for Trials Between Academic Groups and Pharmaceutical Companies - 2010**

## 2. ENGOT documentation checklist

| Checklist and/or handbook | Document last version | Location | Status | Description |
|---|---|---|---|---|

Tasks for leading group NEW

Trial overview NEW

Group representatives

Group participation roster – in preparation NEW

Admin. Chair guide book NEW

List of Mentors NEW

Document checklist NEW

**NEXT ....**

**Ongoing risk based/adaptive monitoring projects:**

**3. Update of ADAMON study and TEMPER study**

Two ongoing initiatives comparing full monitoring vs. adaptive monitoring.

- ADAMON : (number of critical + majors findings) : results published end of the year (non inferiority was reached)
- TEMPER : final analysis planned in September 2016

**4. ICON 6**

Feedback from the audit for the preparation for the file submission **TOPIC Monitoring continues to be important also in light of the upcoming GCP amendment**

## 5. Budgeting a trial

Discussion on how to calculate the hourly rate for each person (study coordinator, study nurse, assistant…)

Next steps = each group will try to estimate hourly rate for next meeting

## 6. Update on EU Regulation and GCP amendment

EMA Work programm 2016:

**Table 1**: Time frame for the implementation of EU portal and EU database

| EU portal and EU database delivery time frame | | |
|---|---|---|
| | **Activity** | **Date** |
| 1. | Auditable Version released for audit, including implementation of auditable and non-auditable must requirements | July 2017 |
| 2. | Independent Audit commences | August 2017 |
| 3. | Development of remaining requirements commences | August 2017 |
| 4. | Independent Audit completed | November 2017 |
| 5. | Audit endorsed by EMA Management Board | December 2017 |
| 6. | European Commission notice published in *Official Journal of the European Union* | March 2018 |
| 7. | Production Version completed, including implementation of remaining should requirements | July 2018 |
| 8. | Production Version go-live | September 2018 |
| 9. | Regulation (EU) No 536/2014 becomes applicable | October 2018 |
| 10. | Further upgrade and enhancement of the system completed | Q3 2019 |
| 11. | Directive on Clinical Trials 2001/20/EC no longer applicable | October 2021 |

**7. ENGOT monitoring network**

**Aim : better position when presenting ENGOT to Pharma**

**a) survey sent to each group to identify a representative : each group identified someone**

**b) next steps : to contact each rep from each group to ask specific questions about monitoring**