Organization of clinical trials in hospitals

By Tina November CSC UZ- Leuven

UZ Leuven, het eerste Belgische ziekenhuis met het internationale JCI-label voor veilige en kwaliteitsvolle zorg.

UZ Leuven | Herestraat 49 B - 3000 Leuven | www.uzleuven.be tel. +32 16 33 22 11

UNIVERSITY HOSPITALS LEUVEN

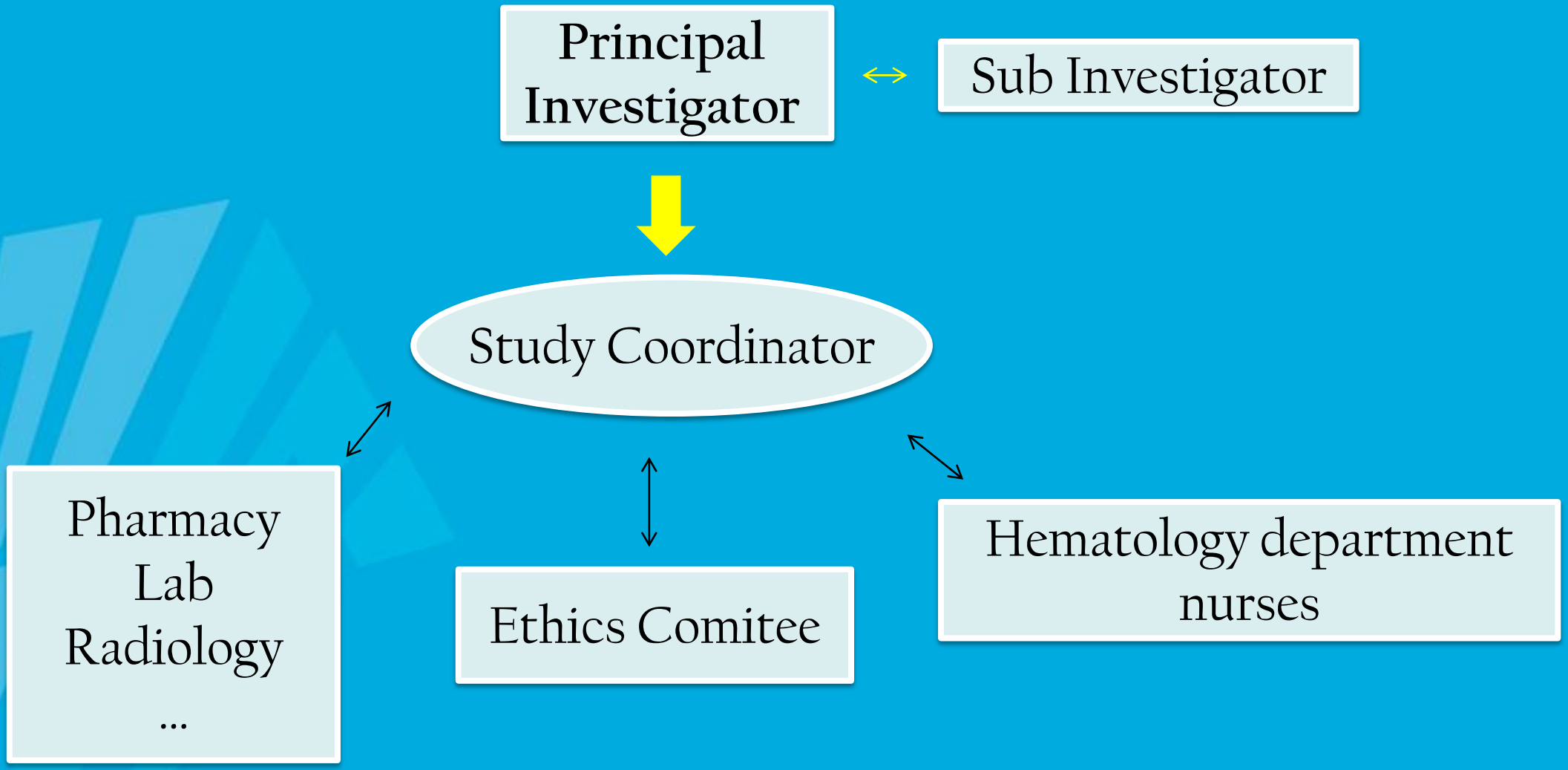
Different types of studies:

- Organized by:
  - Companies
  - Scientific organisations (EORTC, HOVON, EBMT, IFM, GELA....)
  - Investigator (local initiatives)

Study steps:

- (Do-ability)
- Feasibility
- EC approval (protection of patient)
- Initiation visit
- Start of enrollment
- End of treatment – fup -survival
- Study closure (last patient last visit)
- Close site = closing visit and archiving (20 years)
- Publication, Clinical study report (Results)

Involved in the study at site:



Role of the study coordinator

- Coordination
- Compliance with protocol (samples, procedures, medication)
- Contact between all partners
- Data collection and entry (e-CRF)
  - Monitoring
- Support inspections and audits
- Patient support
- ….

Key documents

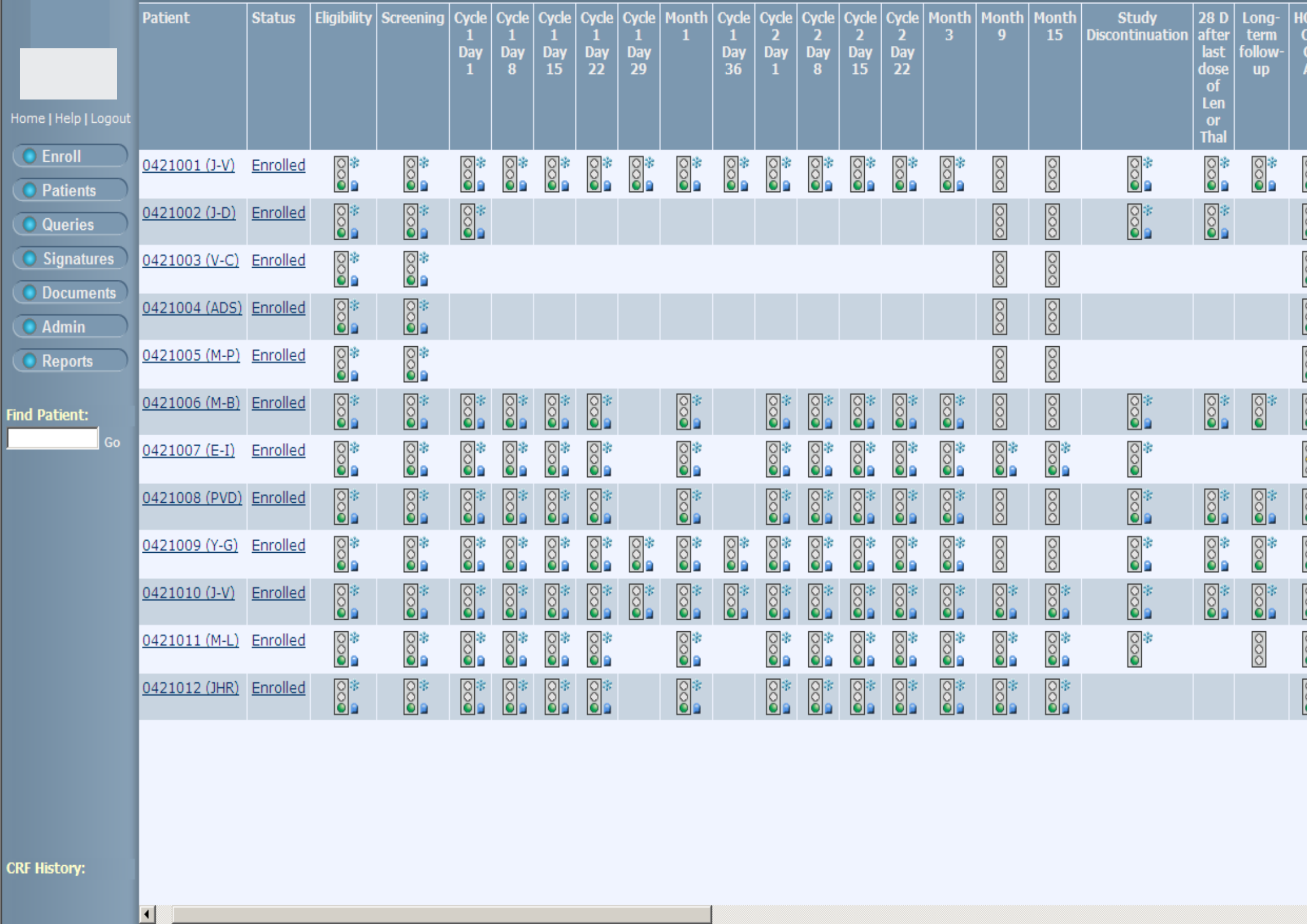
- Protocol
  - describes all procedures
    - in and exclusion criteria (in detail) no deviations allowed
    - flow chart – example

TIME AND EVENTS SCHEDULE*

Procedure	Screening	Cycles 1- 6 (and 7-8, if applicable)				Response Evaluation[d] Days 11-21 of Cycles 2, 4, 6 (and 8, if applicable)	Early Withdrawal/ End-of-Treatment Phase[e]	Short-term Follow-up[f] until PD/initiation alternate therapy/withdrawal	Long-term Follow-up[g] until death
		Day1	Day4	Day 8	Day 11				
Informed consent	X								
Inclusion/ Exclusion	X								
Demographics/Medical history	X								
Complete physical examination	X					X	X		
Limited physical examination[a]		X[a]	X	X	X			X	
ECOG performance status	X	X[a]				X	X	X	
Vital signs		X[a]	X	X	X	X	X	X	
Weight/Height		X[a]					X	X	
BSA		X[a]							
ECG	X	X[a]					X		
Echocardiogram/MUGA scan[a]	X								
Neck and chest CT with oral and i.v. contrast[b]	X					X	X	X	
Abdomen and pelvis CT with oral and i.v. contrast[b]	X					X	X	X[cc]	
Evaluation of other sites of disease[c]	X					X	X	X[cc]	
Bone marrow aspirate and biopsy	X[j]					X[d]	X[d]	X[d]	
Hematology[i]	X	X[a]	X[bb]	X[bb]	X[bb]	X	X		
Clinical Chemistry[ff]	X	X[a]				X	X	X[a]	
Serum/Urine β-HCG pregnancy test (for females)	X	X[a,x]					X		
PRO (EORTC-QLQ-C30, EQ5D, BFI)[o]	X	X					X		
Medical resource utilization[r]		X					X	X	

Key documents

- Protocol
  - describes all procedures
    - in and exclusion criteria (in detail) no deviations allowed
    - flow chart – example
    - Dosage and administration
    - Study evaluations
    - Dose modifications
- eCRF to collect data (paper vs electronic) of every single patient example


Home | Help | Logout
Enroll
Patients
Queries
Signatures
Documents
Admin
Reports
Find Patient:
Go
CRF History:
Patient
Status
Eligibility
Screening
Cycle 1 Day 1
Cycle 1 Day 8
Cycle 1 Day 15
Cycle 1 Day 22
Cycle 1 Day 29
Month 1
Cycle 1 Day 36
Cycle 2 Day 1
Cycle 2 Day 8
Cycle 2 Day 15
Cycle 2 Day 22
Month 3
Month 9
Month 15
Study Discontinuation
28 D after last dose of Len or Thal
Long-term follow-up
0421001 (J-V) Enrolled
0421002 (J-D) Enrolled
0421003 (V-C) Enrolled
0421004 (ADS) Enrolled
0421005 (M-P) Enrolled
0421006 (M-B) Enrolled
0421007 (E-I) Enrolled
0421008 (PVD) Enrolled
0421009 (Y-G) Enrolled
0421010 (J-V) Enrolled
0421011 (M-L) Enrolled
0421012 (JHR) Enrolled

Tina November

Home | Help | Logout

Enroll
Patients
Queries
Signatures
Documents
Admin
Reports

Find Patient:
Go

HEMATOLOGY

Patient: J-V/0421001

Hematology

1.*	Collection Date	30/Jun/2009

Results

2.*	Red Blood Cells	*Result:* 3.83 Clinically Significant No *Units:* 10^12/L
3.*	Hemoglobin	*Result:* 12.5 Clinically Significant No *Units:* g/dL
4.*	Hematocrit	*Result:* 0.354 Clinically Significant No *Units:* Proportion of 1.0
5.*	Platelets	*Result:* 196.0 Clinically Significant No *Units:* 10^9/L
6.*	White Blood Cell Count	*Result:* 5.5 Clinically Significant No *Units:* 10^9/L
7.*	Absolute Lymphocytes	*Result:* 1.7 Clinically Significant No *Units:* 10^9/L
8.*	Absolute Neutrophils	*Result:* 3.2 Clinically Significant No *Units:* 10^9/L
9.*	Basophils	*Result:* 0.4 Clinically Significant No *Units:* %
10.*	Eosinophils	*Result:* 2.7 Clinically Significant No *Units:* %
11.*	Lymphocytes	*Result:* 31.0 Clinically Significant No *Units:* %
12.*	Monocytes	*Result:* 8.4 Clinically Significant No *Units:* %
13.*	Neutrophils	*Result:* 57.5 Clinically Significant No *Units:* %

CRF History:
042:J-V:C1D1:HEMA
042:J-V:C1D1:DOV

Tina November

EORTC QLQ-C30

Patient: J-V/0421001

Health Information		
1.*	Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	Not at All
2.*	Do you have any trouble taking a long walk?	Not at All
3.*	Do you have any trouble taking a short walk outside of the house?	Not at All
4.*	Do you need to stay in bed or a chair during the day?	Not at All
5.*	Do you need help with eating, dressing, washing yourself or using the toilet?	Not at All
During the past week:		
6.*	Were you limited in doing either your work or other daily activities?	Quite a Bit
7.*	Were you limited in pursuing your hobbies or other leisure time activities?	Quite a Bit
8.*	Were you short of breath?	Very Much
9.*	Have you had pain?	Very Much
10.*	Did you need to rest?	Quite a Bit
11.*	Have you had trouble sleeping?	Not at All
12.*	Have you felt weak?	A Little
13.*	Have you lacked appetite?	Not at All
14.*	Have you felt nauseated?	Not at All
15.*	Have you vomited?	Not at All
16.*	Have you been constipated?	Quite a Bit
17.*	Have you had diarrhea?	Not at All
18.*	Were you tired?	A Little

Key documents

- Protocol
- e-CRF to collect data (paper vs electronic) of every single patient example
- Informed consent form
- Lab manual
- Pharmacy manual
- Study files

Specific role of the hospital nurse in clinical studies

- Understand and explain importance of clinical research
- Motivate, support patients
- Safety monitoring: report side effects AE's, SAE's
- Compliance with study procedures (samples, medication)
- Be involved and proactive - challenge the PI – SC
- Extra scientific dimension to the job
- It is also up to you

Quality Key factors

- Protocol compliance
- Not documented = Not done
- Inconsistencies: ex. 2 diff admin hours

Involved in the study at site: