Erasmus MC
University Medical Center Rotterdam

Sophia Children's Hospital

The clinical research co-ordinator, what does this involve?

Els van der Wiel, clinical research coordinator

Pediatric pulmonology

Erasmus MC-Sophia, Rotterdam, the Netherlands

Legal framework

National laws

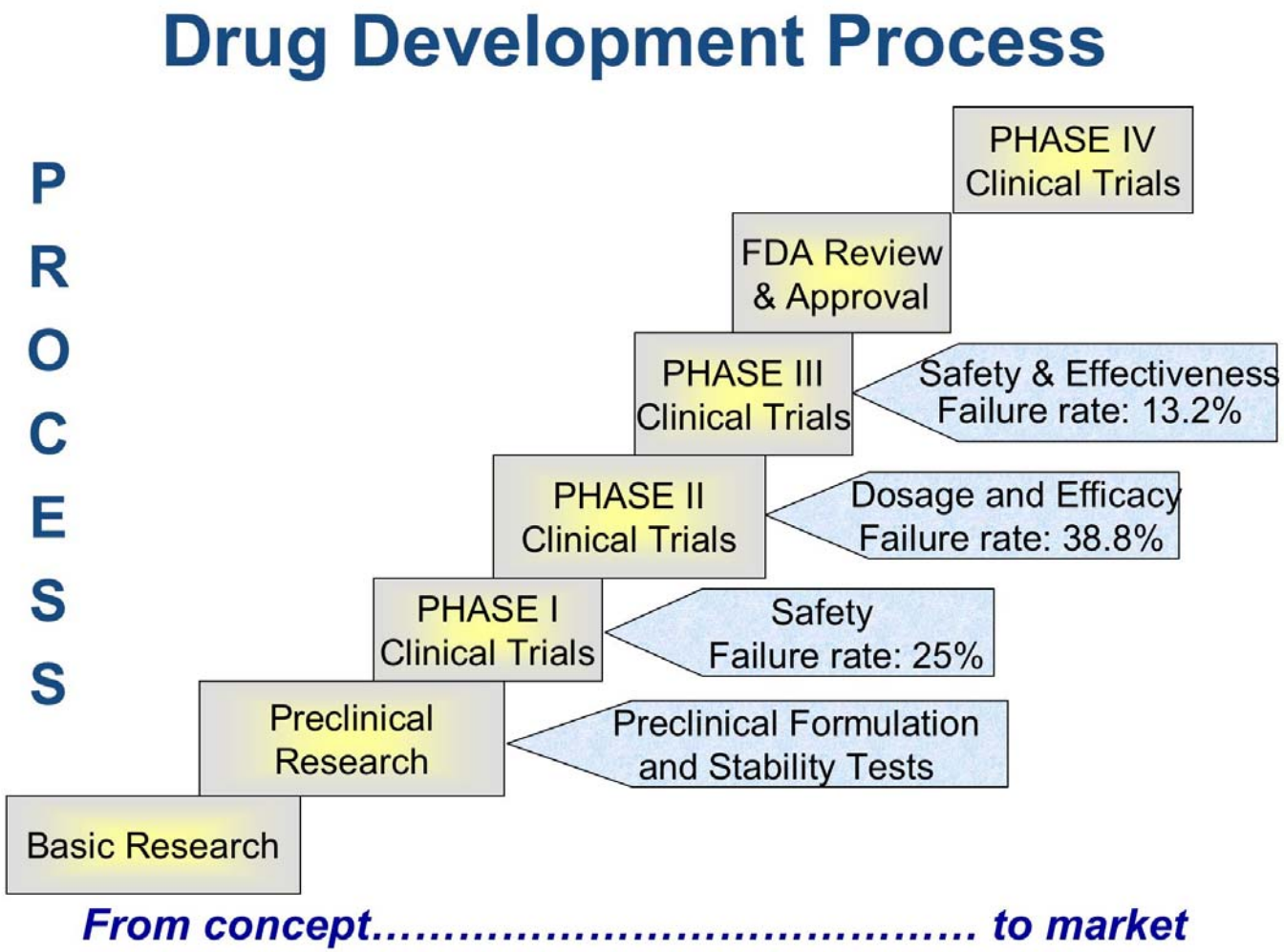
European laws:

- The clinical trials directive (2001)
- The GCP Directive (incorporated ICH-GCP guidelines)

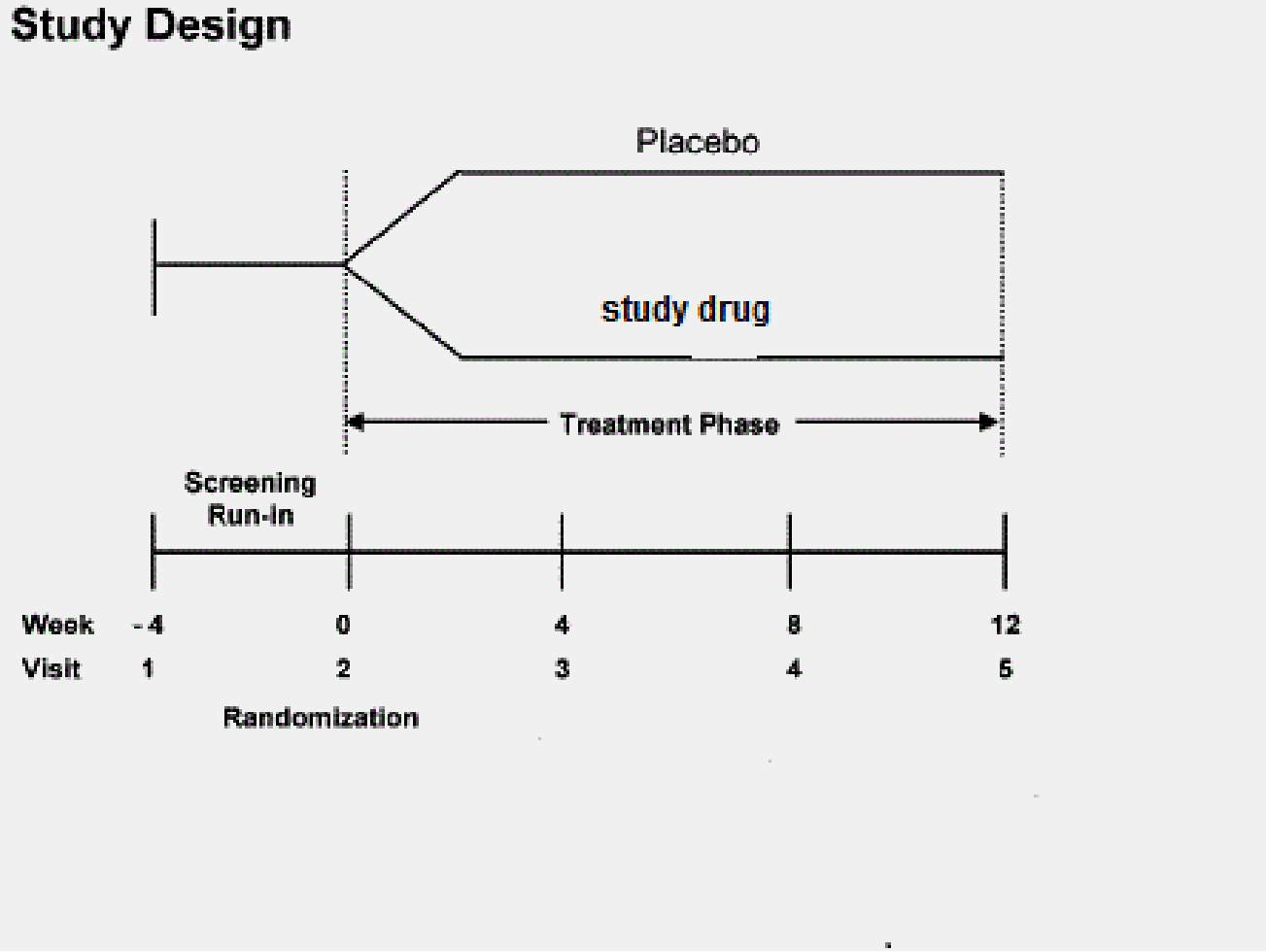
► the rights, safety and wellbeing of trial subjects are protected

► the clinical trial data are credible

Medical research



Phase III, randomised,double blind, placebo controlled trial



Who are involved?

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Pharmaceutical company

CRO

ECFS-CLINICAL TRIALS NETWORK

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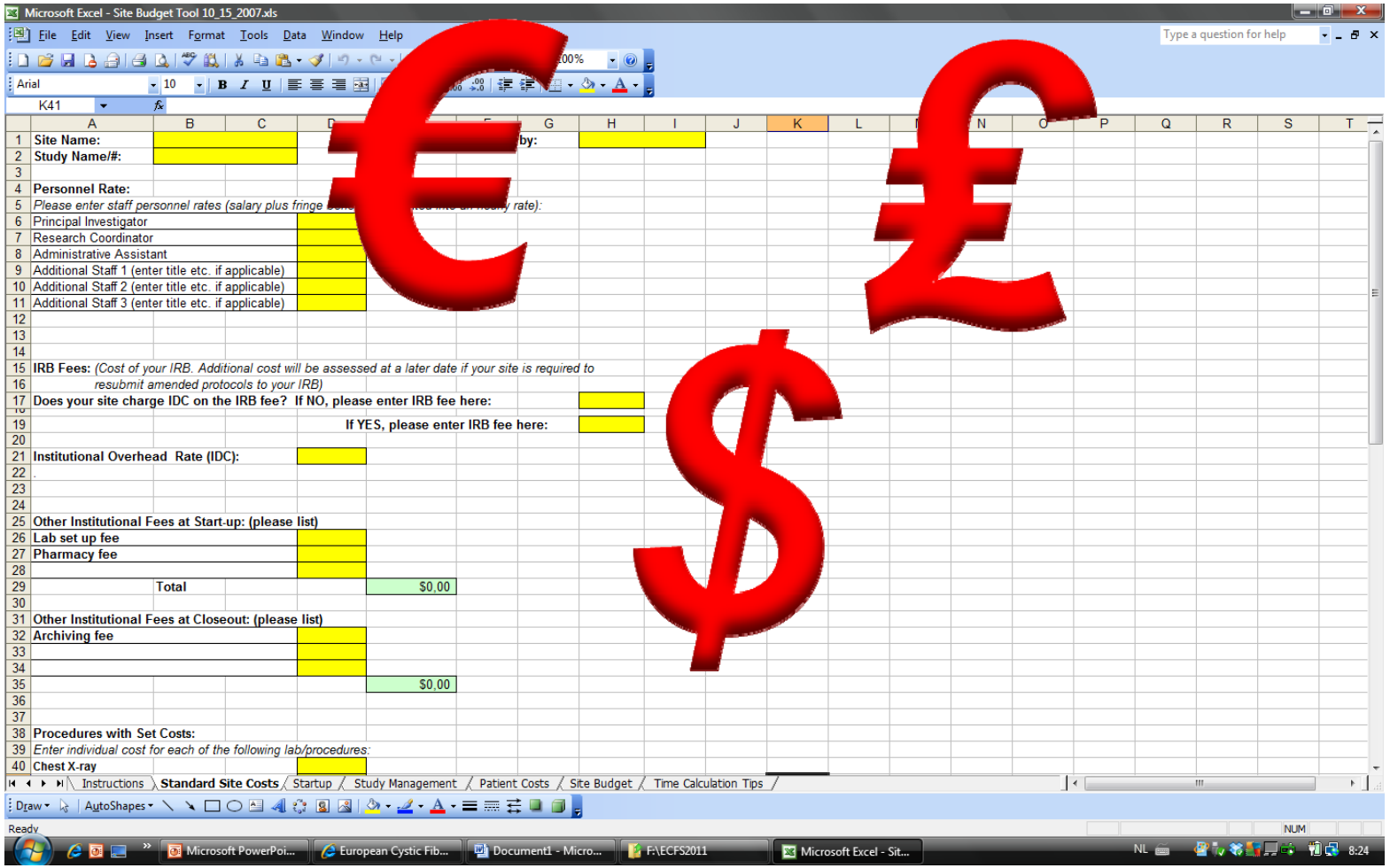
Site budget tool



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Patient protection

Elements of patient information form and Informed Consent form

- purposes of the research
- description of the procedures
- duration of the study
- foreseeable risks and discomforts and possible benefits
- confidentiality of records identifying the patient
- participation is voluntary
- independent physician
- Insurance
- Data kept for 15 years

Children in clinical trials

Only participant in clinical trial when:

- No greater than minimal risk
- More than minimal risk but
  - with the prospect of direct benefit to individual subjects
  - likely to yield generelisable knowledge about subjects disorder
  - not otherwise approvable that the trial presents an opportunity to understand,prevent or alleviate a serious problem affecting the health of the subject

Parents - Informed Consent

Children - Informed Assent

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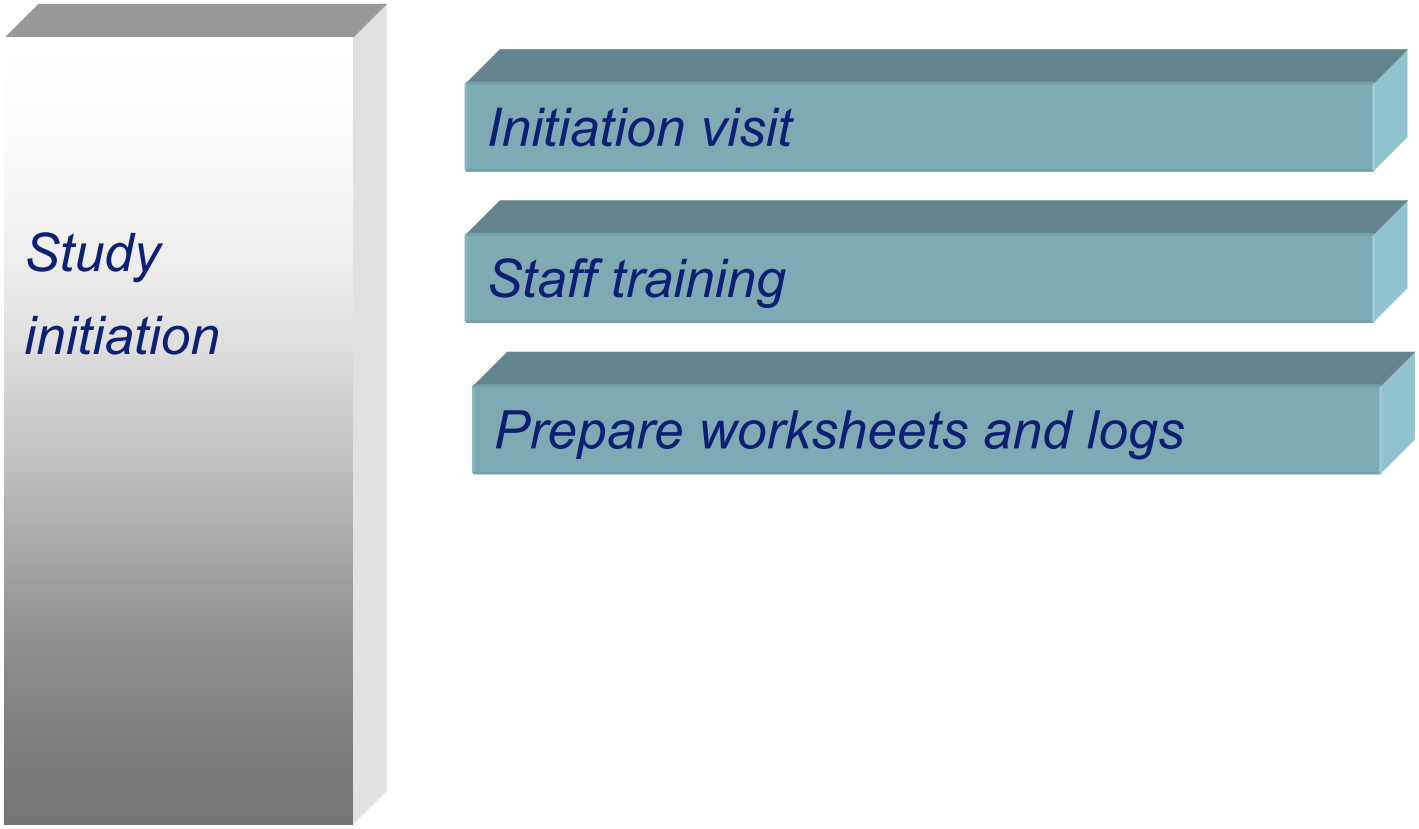

Example - flow chart

ENTRESOL study XYZ -990									
procedure	visit	1 scr.	2	3	4	5	6	7	8
	days	14 ± 2 days	14 ± 2 days	14 ± 2 days	14 ± 2 days	14 ± 2 days	14 ± 2 days	14 ± 2 days	14 ± 2 days
informed consent		x							
in-exclusion criteria		x							
demografic data		x							
medical history		x							
concomitant treatment		x	x	x	x	x	x	x	x
physical examination		x							x
FVC, FEV1		x	x	x	x	x	x	x	x
vital signs		x	x	x	x	x	x	x	x
blood draw safety			x						x
urine safety			x						x
QoL questionnaire		x			x				x
ecg			x						x
adverse events			x	x	x	x	x	x	x
compliance studiemed			x	x	x	x	x	x	x
return study medication			x	x	x	x	x	x	x
study discharge									x

Example - sample timing calculator

Microsoft Excel - PK Sample Timing Calculator Tool.xls

	A	B	C	D	E
1	**Timepoint**	**Actual Time**		**Timepoint**	**Actual Time**
2	-0-	0:00		+12hrs	12:00
3	+10	0:10		+16hrs	16:00
4	+15	0:15		+18hrs	18:00
5	+20	0:20		+24hrs	0:00
6	+30	0:30		+36hrs	12:00
7	+45	0:45		+48hrs	0:00
8	+60	1:00		+72hrs	0:00
9	+90	1:30			
10	+2hrs	2:00		**Instructions: Type in your actual start time in the black box. It must be in**	
11	+2.5hrs	2:30		**the format 08:00. Do not type in any other boxes. The program will**	
12	+3hrs	3:00		**calculate the other times for you.**	
13	+4hrs	4:00			
14	+5hrs	5:00			
15	+6hrs	6:00			
16	+7hrs	7:00			
17	+8hrs	8:00			
18	+9hrs	9:00			
19	+10hrs	10:00			
20					

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Running the study

- *Patient screening and enrollment*
- *Check study procedures*
- *CF Team meetings*
- *CRA contacts: monitor visits, (S)AE*
- *Data collection in compliance with protocol*

Deficiencies from conducting clinical trials

FDA inspections

- Protocol violations, (failure to adhere from the clinical protocol)
- Inadequate subject protection – including problems with IC
- Inadequate drug accountability
- Inadequate/incorrect records
- Failure to report adverse drug reactions, adverse events and serious adverse events

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Essentials for trial participation

- Positive attitude towards research
- Adequate staffing and ancillary support
- Adequate patient pool
- An understanding of your patients
- Effective screening process
- Effective communication
- Adequate training and education
- Local research standard operating procedures (SOPs)
- Ability to conduct the required study procedures

- PI + CRC + other team members =

So ..what is the role of the CRC?

The CRC is responsible for the coordination, management and conduct of clinical trials using GCP under the auspices of a designated investigator.

Other aspects of the role of the CRC

- **Several trials at the same time (investigator / sponsor initiated)**
- **Enhance research committment, research quality (SOP's, training)**
- **Committee member :IRB,Protocol review committee**
- **Coaching of PhD students**

Skills

Excellent communication
Strong interpersonal skills
Good organisation skills
Attention to detail
Proficiency in computers and documentation
Knowledge on research procedures
Knowledge on regulatory requirements
Ability to multitask