



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

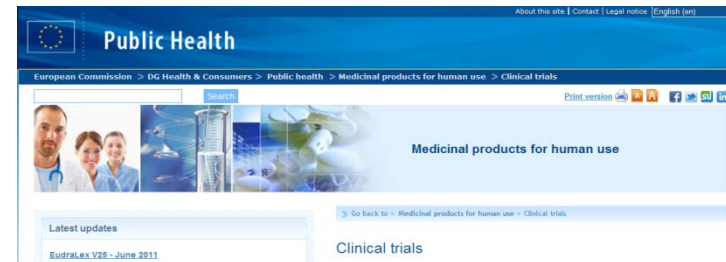
Els van der Wiel, clinical research coordinator  
Pediatric pulmonology  
Erasmus MC-Sophia, Rotterdam, the Netherlands

# Legal framework

National laws

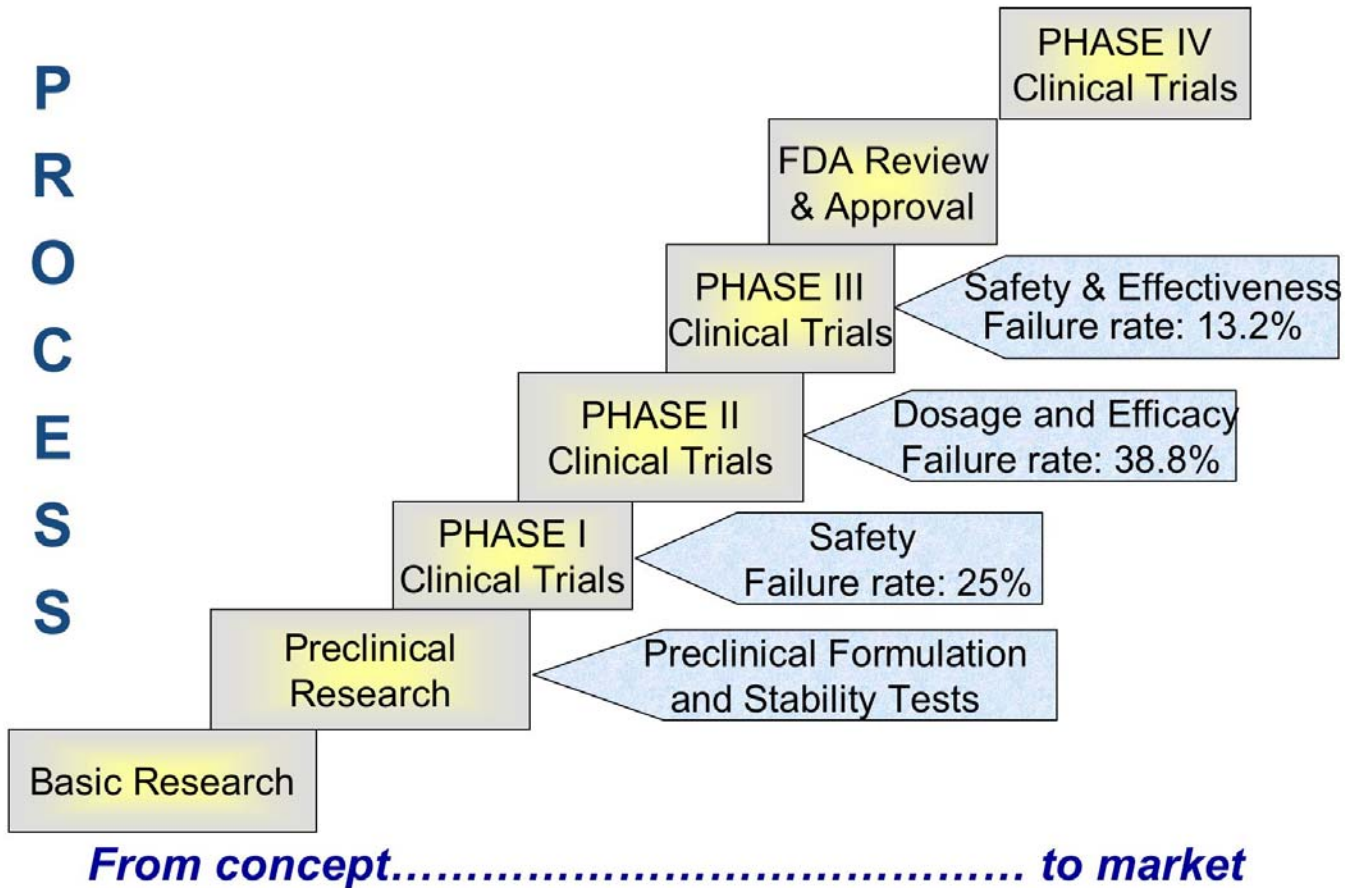
European laws:

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

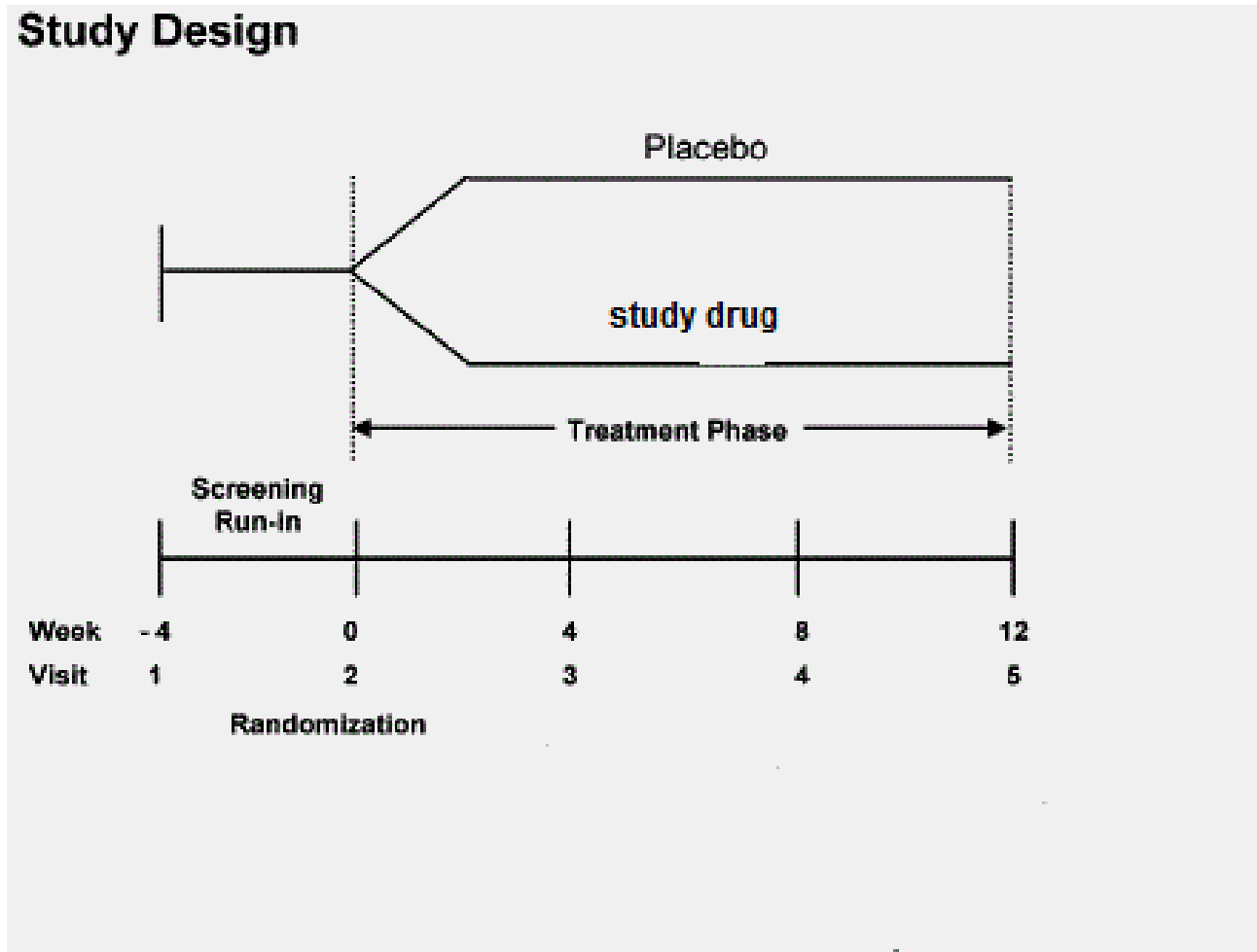


- ▶ the rights, safety and wellbeing of trial subjects are protected
- ▶ the clinical trial data are credible

# Drug Development Process



# Phase III, randomised, double blind, placebo controlled trial



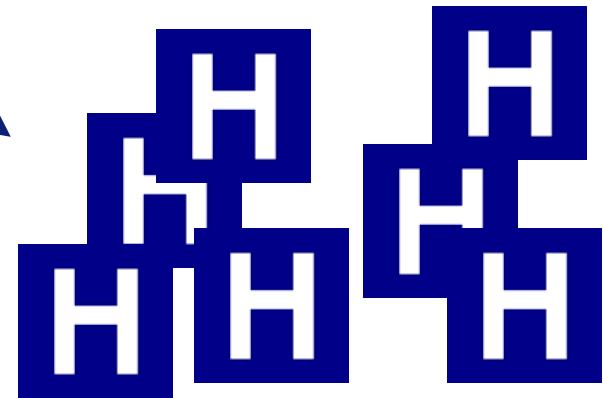
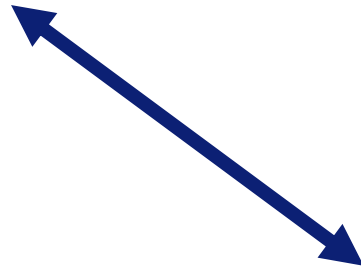
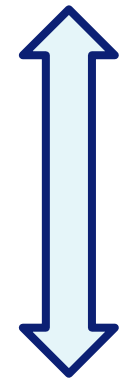
# Who are involved?



Pharmaceutical company

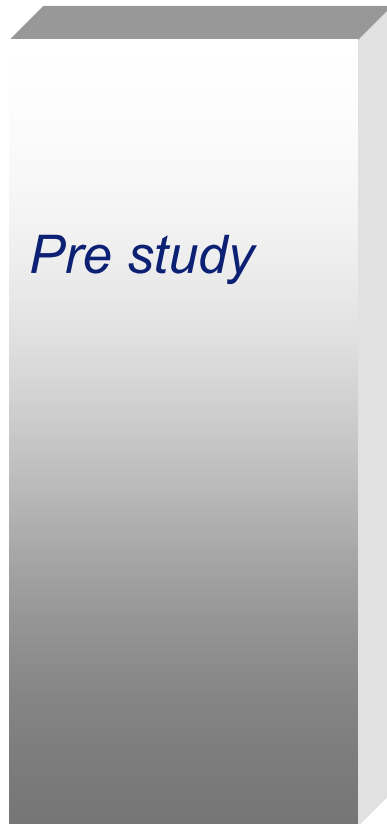


CRO





# Managing a clinical trial in a study centre



*First contacts with CRO*

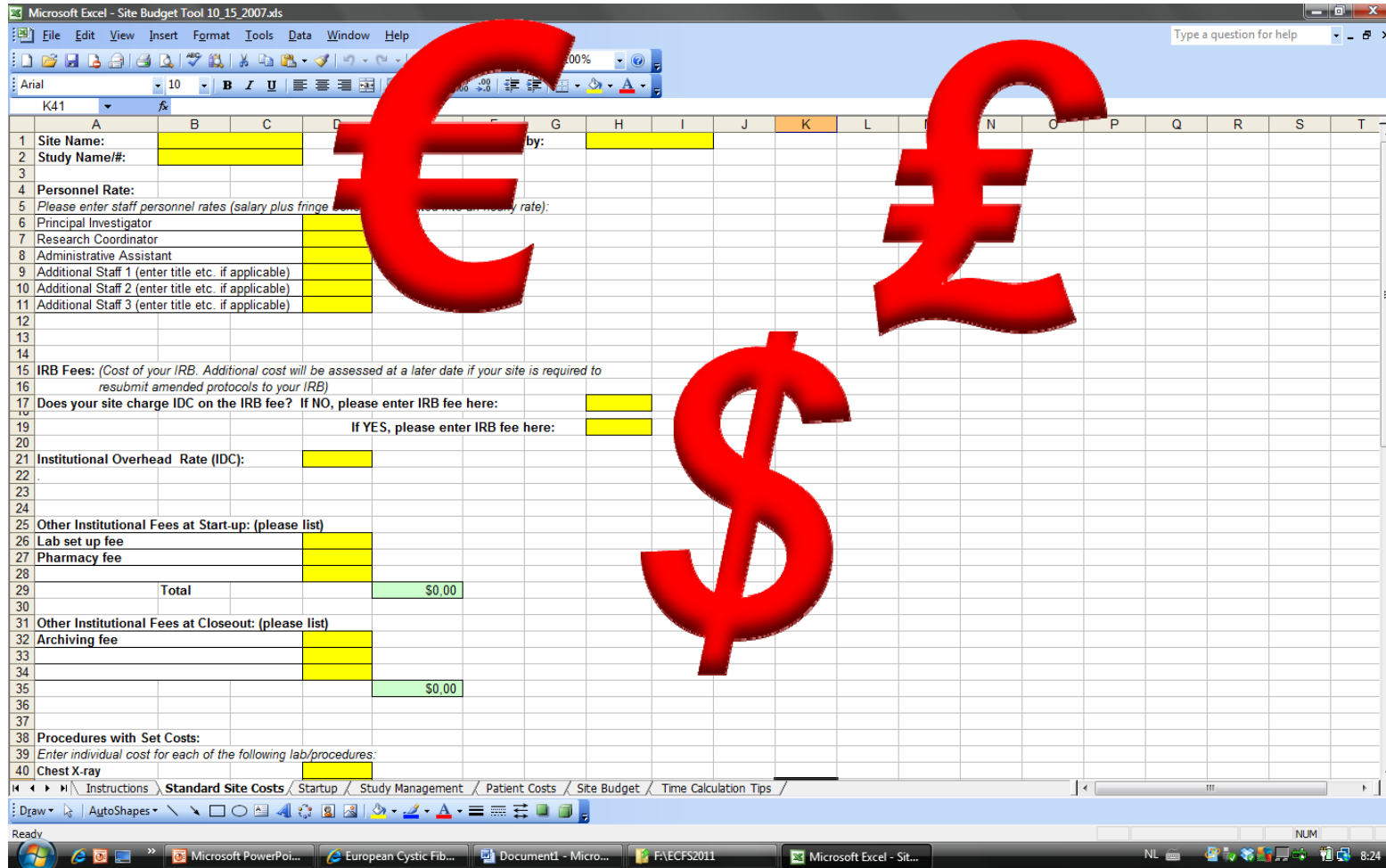
*CF Team meeting*

*Contract and budget negotiations*

*Investigator meeting*

*IRB submission*

# Site budget tool

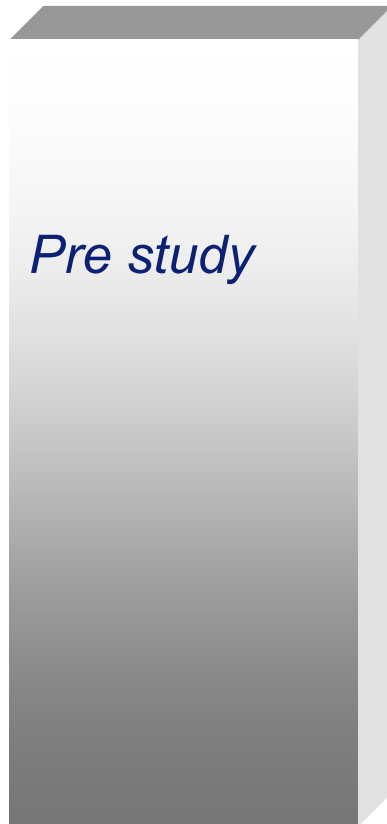


The screenshot shows the 'Site Budget Tool 10.15.2007.xls' spreadsheet. The interface includes a menu bar (File, Edit, View, Insert, Format, Tools, Data, Window, Help), a toolbar, and a grid of cells. The spreadsheet is divided into sections for personnel, IRB fees, and other institutional costs. Large red 3D currency symbols (Euro, Pound, and Dollar) are overlaid on the spreadsheet. The 'Personnel Rate' section (rows 4-11) lists roles like Principal Investigator, Research Coordinator, and Administrative Assistant. The 'IRB Fees' section (rows 15-20) asks if the site charges IDC on the IRB fee. The 'Other Institutional Fees at Start-up' section (rows 25-29) includes Lab set up fee, Pharmacy fee, and a Total of \$0.00. The 'Other Institutional Fees at Closeout' section (rows 31-35) includes Archiving fee and a Total of \$0.00. The 'Procedures with Set Costs' section (rows 38-40) lists Chest X-ray. The bottom of the window shows the Windows taskbar with various open applications and the system clock at 8:24.

Row	Column	Text	Value
1	A	Site Name:	
2	A	Study Name/#:	
4	A	Personnel Rate:	
5	A	Please enter staff personnel rates (salary plus fringe benefits plus insurance plus monthly rate):	
6	A	Principal Investigator	
7	A	Research Coordinator	
8	A	Administrative Assistant	
9	A	Additional Staff 1 (enter title etc. if applicable)	
10	A	Additional Staff 2 (enter title etc. if applicable)	
11	A	Additional Staff 3 (enter title etc. if applicable)	
15	A	IRB Fees: (Cost of your IRB. Additional cost will be assessed at a later date if your site is required to resubmit amended protocols to your IRB)	
17	A	Does your site charge IDC on the IRB fee? IF NO, please enter IRB fee here:	
19	A	If YES, please enter IRB fee here:	
21	A	Institutional Overhead Rate (IDC):	
25	A	Other Institutional Fees at Start-up: (please list)	
26	A	Lab set up fee	
27	A	Pharmacy fee	
29	A	Total	\$0.00
31	A	Other Institutional Fees at Closeout: (please list)	
32	A	Archiving fee	
35	A	Total	\$0.00
38	A	Procedures with Set Costs:	
39	A	Enter individual cost for each of the following lab/procedures:	
40	A	Chest X-ray	



# Managing a clinical trial in a study centre



- First contact with CRO*
- CF Team meeting*
- Contract and budget negotiations*
- Investigator meeting***
- IRB submission***



## 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 generalisable 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

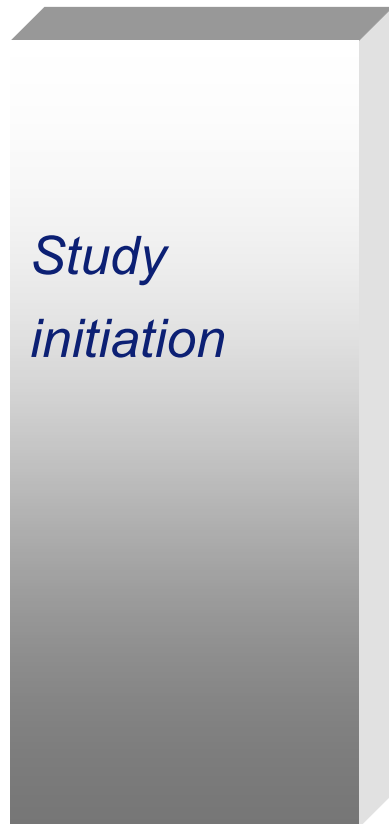
Parents - Informed Consent

Children - Informed Assent





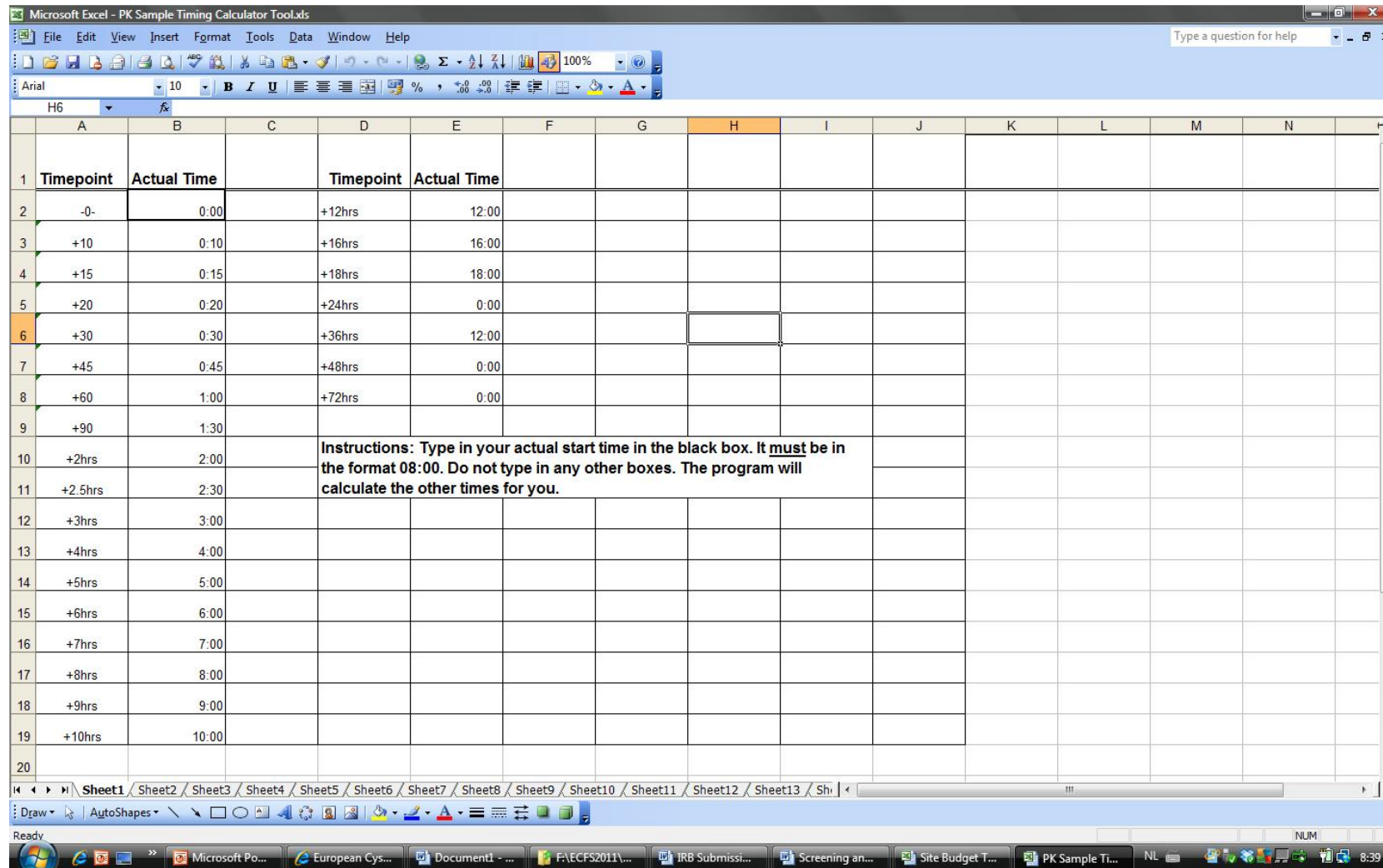
# Managing a clinical trial in a study centre



## 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							
demographic 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



The screenshot shows a Microsoft Excel spreadsheet titled "PK Sample Timing Calculator Tool.xls". The spreadsheet contains a table with columns for "Timepoint" and "Actual Time". The data is as follows:

	A	B	C	D	E	F	G	H	I	J	K	L	M	N
1	<b>Timepoint</b>	<b>Actual Time</b>		<b>Timepoint</b>	<b>Actual Time</b>									
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	<b>Instructions: Type in your actual start time in the black box. It <u>must</u> be in the format 08:00. Do not type in any other boxes. The program will calculate the other times for you.</b>											
11	+2.5hrs	2:30												
12	+3hrs	3:00												
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														

The spreadsheet also shows a taskbar at the bottom with several open applications, including "Microsoft Po...", "European Cys...", "Document1 - ...", "F:\ECFS2011\...", "IRB Submissi...", "Screening an...", "Site Budget T...", "PK Sample Ti...", and "NL". The system clock shows 8:39.



# Managing a clinical trial in a study centre

*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

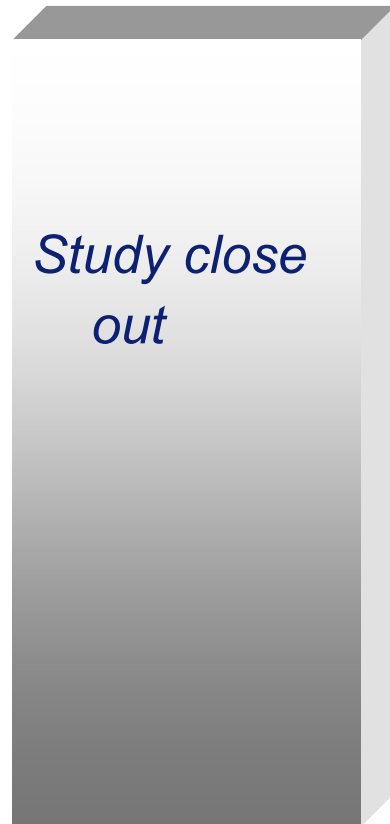
FDA inspections

- 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





## Managing a clinical trial in a study centre



*Final team meeting*

*Close out visit with CRO*

*Data handling*

*Inform authorities*

*Patient thank you letter*



## 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 commitment, 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