

DISCHARGE eCRF

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Tasks of data management

- Administration of study software secuTrial®
- Designing, creating, programming of electronic Case Report Forms (eCRF)
- Managing, coordinating and processing of incoming information
- Design, programming and administration of our database
- Data validation
- Data handling
- Help and support on technical aspects

Availability of secuTrial®

- Server online 23.5/7
 - » Integrated in Charité IT service
 - » New hardware coming soon

- World-wide reachable
 - » Access with every standard internet browser
 - » Standard configuration
 - » No further software installation necessary

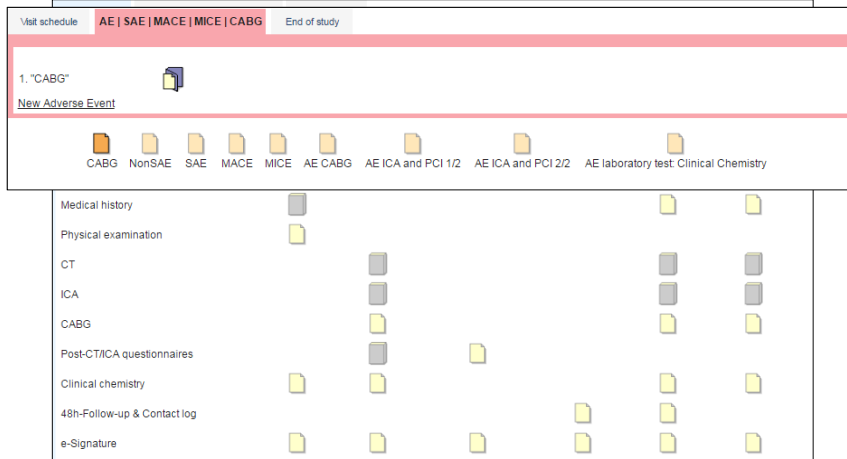
Overview

- Discharge has become our biggest project.
- At least 9 times more complex to the average of our other studies.
- At least 8 times more items than our second most complex study!
- 8 times more items than our second most complex study!

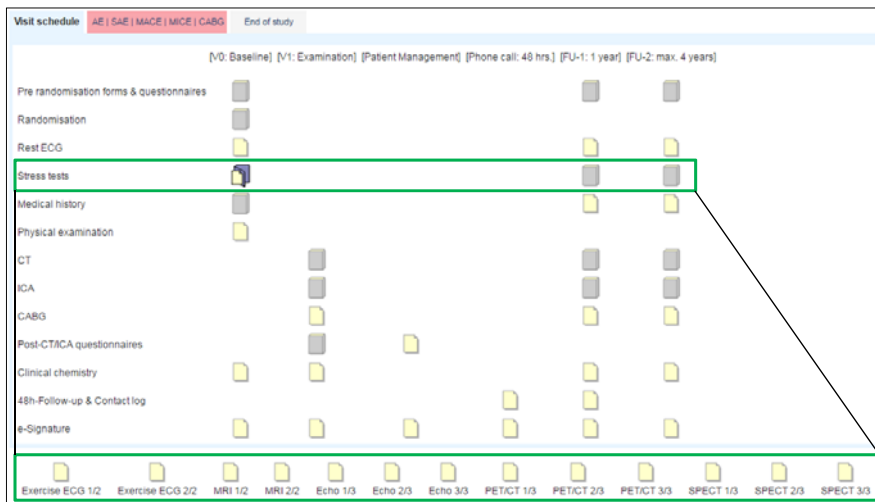
Active studies (Studies on one out of three reports)				
	Forms	Question	Items	Rules
A*	77	269	875	995
B*	34	269	914	821
B*	98	1281	3653	5794
Z:	56	947	843	1115
C*	97	1518	2664	5199
C*	46	293	575	748
C	22	242	913	1164
L*	37	385	765	1213
I*	111	1483	1915	103
m*	27	353	654	741
M*	73	961	1534	1519
P*	37	374	747	1114
R*	24	655	600	549
R*	58	757	1200	1690
S*	50	605	865	1058
S*	46	399	772	1180
T*	14	200	453	345
	Forms	Question	Items	Rules
DISCHARGE	448	7163	15266	14871
Average	50,35	655,88	1143,59	1491,06
	Forms	Question	Items	Rules
Discharge to average	890%	1092%	1335%	997%

Finalization

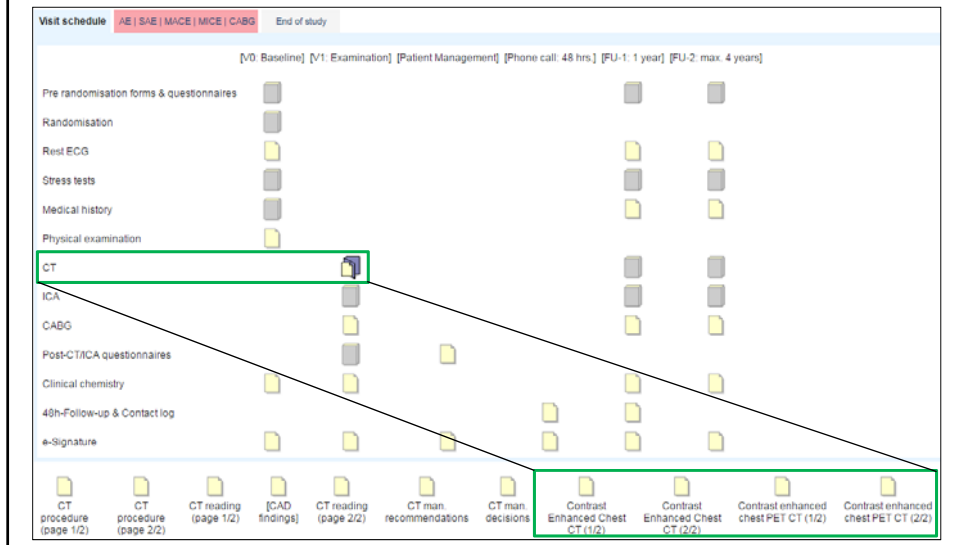
- Visit schedule



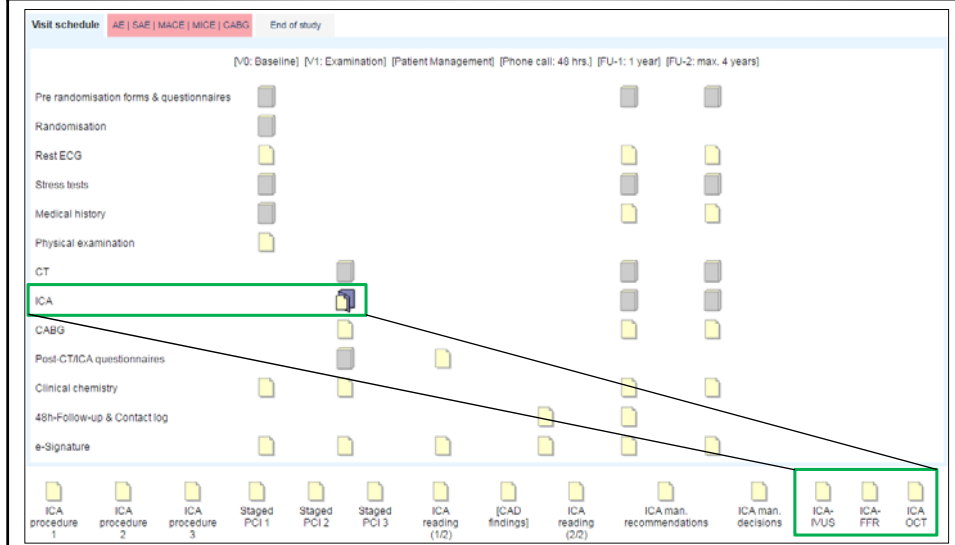
Finalization – Visit schedule



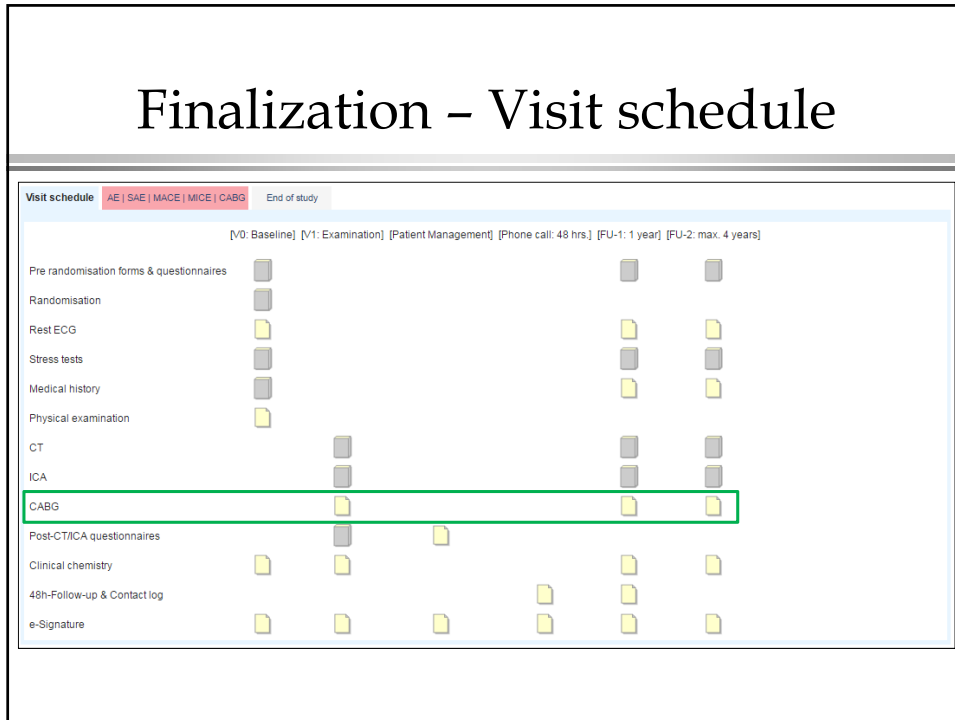
Finalization – Visit schedule



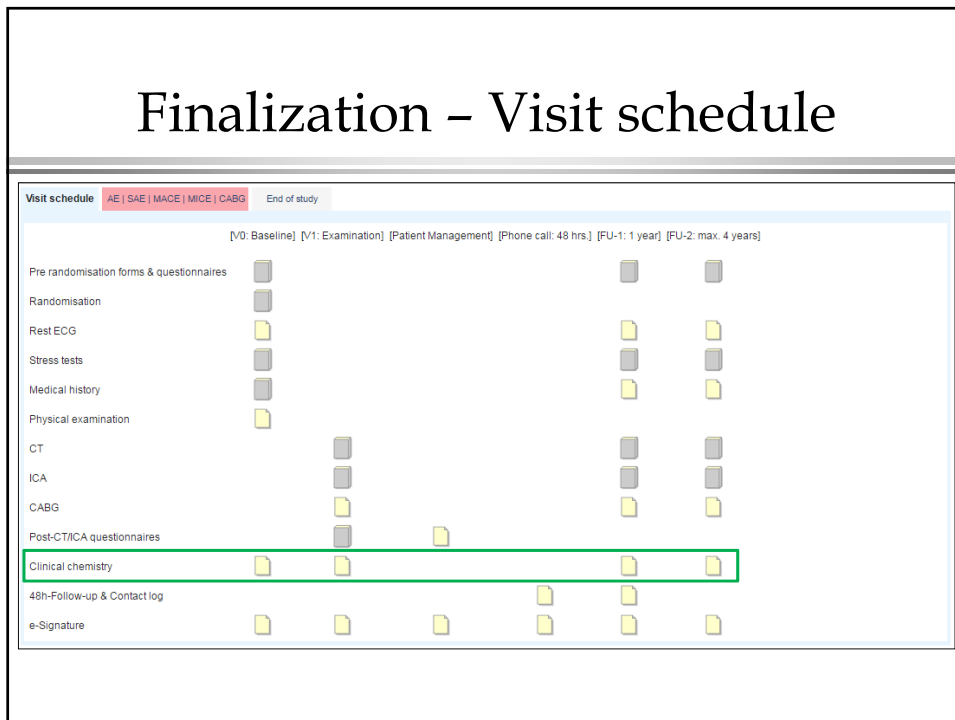
Finalization – Visit schedule



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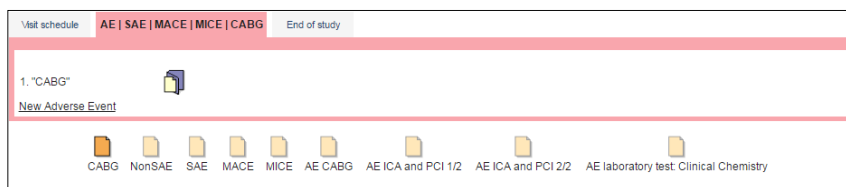


Finalization – Visit schedule



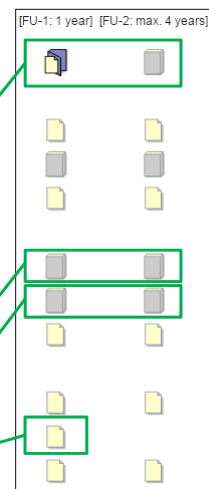
Finalization – AE forms

- MICE
- CABG
- ICA & PCI
- Clinical chemistry



Finalization – Dedicated FU forms

- FU staff form
- FU questionnaire form (patient)
- SES, QoL & Lifestyle (staff form) FU
- Documentation of additional hospitalisations
- Documentation of emergency department visits
- Documentation of additional physician visits
- Follow-up CT
- Follow-up ICA and PCI
- FU 1 Contact Log



Help and contact, at the end of every pages

- Your contact for questions regarding data entry:
- Felix Frömel
- Coordinating Centre for Clinical Studies (KKS Charité)
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Thank you for your attention

Any questions?

