

# Electronic systems in clinical trials Investigator's perspective

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# Conflicts of interest

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## **Principal investigator in phase II-IV trials sponsored by:**

Astellas, Astra Zeneca, Boehringer-Ingelheim, Daiichi Sankyo, Eurocine, Grünenthal, Glaxo Smith Kline, Janssen Cilag, Karo Bio, Moberg Pharma, Merck Sharpe & Dome, Mundipharma, Novartis, Pfizer, Sanofi Aventis, SCA, Smartfish, Takeda, (*Wyeth, Shearing-Plough*)

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## **Also working together with the following organizations and CRO's:**

ICON, INCRResearch, InventiveHealthResearch, IRW, PAREXEL, PCG, Quintiles, TFS, TIMI Group, WWCTrials (*Commitum, I3-R, Pharmanet*)



# LADULAAS

KLINISKA STUDIER

## DET PERSONLIGA PRÖVNINGSCENTRET

Klinisk prövning av...

- o Läkemedel
- o Medicintekniska produkter

Företaget med...

- o Lång erfarenhet
- o Hög kompetens
- o God kontinuitet
- o Hög säkerhet
- o Snabb rekrytering
- o Korta beslutsvägar
- o Låg frekvens "drop-outs"

*Try us for trials!*



LADULAAS  
KLINISKA STUDIER



# Explosion in number of systems during recent years

Field of invest	Start	Training-P	IWRS	e-CRF	SUSAR-P	Study-P	E-Diary	Site-PAD	C-ECG	C- Spiro	Lab	Device	ABPM	Systems
Diab type II	2012		x	x	x									3
Cardioprotective	2012		x	x	x				x					4
Diab Type II	3013		x	x	x									3
OAB 1	2014	x	x	x	x		x	x	x				x	8
OAB 2	2014	x	x	x	x		x	x	x					7
Diab Type I	2015		x	x	x	x					x			5
COPD	2015		x	x	x	x	x	x		x				7
COPD/Nutri	2015		x	x			x	x			x			5
Diab Typ II	2015	x	x	x	x	x	x	x	x		x	x		10
Fibromyalgia 1	2015	x	x	x	x	x	x	x	x		x			9
Fibromyalgia 2	2016	x	x	x	x	x	x	x	x		x			9



A SELECTION OF ELECTRONIC EQUIPMENT

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# Overview of devices, systems and support in one study

Device/ equipment	Function	Vendor	Portal/ website	Access to portal/website	Contact details Helpdesk
Log pad	e-diary for patients to enter b-glucose/ketone levels, daily insulin use and hypoglycemic events. Continuous transmission of data via 3G or 4G. Possibility to connect to wifi if signal is bad.	PHT	Study works <a href="https://mystudy.phtstudy.com/ssa">https://mystudy.phtstudy.com/ssa</a>	To be created via <a href="https://mystudy.phtstudy.com/ssa">https://mystudy.phtstudy.com/ssa</a> Make sure that access to this portal is granted prior to start using the devices (48 hours leadtime).	<a href="https://mystudy.phtstudy.com/ssa/pages/contact_us/">https://mystudy.phtstudy.com/ssa/pages/contact_us/</a> Email: <a href="mailto:techsupport@phtcorp.com">techsupport@phtcorp.com</a>
Site Pad	Tablet for patients to electronically complete questionnaires at site. Automatic transmission of data when docked to the docking station. If failed, transmission can be performed via 3G or 4G. Please contact helpdesk for activation of the 3G or 4G card.	PHT	Study works <a href="https://mystudy.phtstudy.com/ssa">https://mystudy.phtstudy.com/ssa</a>	Same access as for the Log pad	<a href="https://mystudy.phtstudy.com/ssa/pages/contact_us/">https://mystudy.phtstudy.com/ssa/pages/contact_us/</a> Email: <a href="mailto:techsupport@phtcorp.com">techsupport@phtcorp.com</a>
CGM	Device for continuous glucose measurements. Data will be manually uploaded into sweetspot,	Dexcom	Sweetspot workstation <a href="http://clinic.sweetspotdiabetes.com/workstation">http://clinic.sweetspotdiabetes.com/workstation</a>	Will be provided via e-mail	Email: <a href="mailto:bi@cts-helpdesk.com">bi@cts-helpdesk.com</a>

## Overview of devices, systems and support in one study.. Cont.

Device/ equipment	Function	Vendor	Portal/ website	Access to portal/website	Contact details Helpdesk
SBGM	Device for the patient to measure b-glucose and ketones at home	Abbot	None. Results will be entered in the e-diary (log pad) and can be reviewed in Study works by site personnel and CRA.	NA	To be found in user guide
Central Lab	Handling of all central laboratory samples in the study.	Qlab	Infosario Informatics <a href="https://infosario.quintiles.com">https://infosario.quintiles.com</a> Laboratory results will be posted here for printout. Re-order of lab supplies can be done via this portal (or via phone/fax or email).	Log in credentials will be provided via email directly from Qlab	Email Quintiles: <a href="mailto:Investigator.services@quintiles.com">Investigator.services@quintiles.com</a>
Courier (for lab samples)	Shipment of lab samples from site to central lab. Supplier of dry ice.	DHL	NA	NA	For ordering of dry ice and pick up of lab samples: DHL EKAS  Please allow at least 24 hours for dry ice delivery.
RDC	Case report form	Oracle	<a href="https://clinicaltrials.boehringer-ingelheim.com">https://clinicaltrials.boehringer-ingelheim.com</a>	Will be provided via email	<a href="mailto:bi@cts-helpdesk.com">bi@cts-helpdesk.com</a>
IRT	Interactive response system for shipment, randomization, dispensing and return of study drug.	Parexel/ Perceptive	<a href="http://www.clinphone.com/signin">www.clinphone.com/signin</a>	User access envelope will be provided by CRA	<a href="http://support.perceptive.com/Support/home.aspx/phones">http://support.perceptive.com/Support/home.aspx/phones</a> ) Support phone numbers can be found via the link above Email: <a href="mailto:customer-care@perceptive.com">customer-care@perceptive.com</a>
Device/ equipment	Function	Vendor	Portal/ website	Access to portal/website	Contact details Helpdesk
BICTP	Safety report and any IB updates are distributed via this system. Sites to confirm receipt.	Oracle	<a href="https://clinicaltrials.boehringer-ingelheim.com">https://clinicaltrials.boehringer-ingelheim.com</a>	Will be provided via email	<a href="mailto:bi@cts-helpdesk.com">bi@cts-helpdesk.com</a>



# Why such a hurry?

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Training equipment and programmed logpads are not in place at IM.

Different vendors for different equipment -- in the end it turns out that they aren't compatible.

Before start we have amendment 3 or 4.

Great waste of time – and time is money for for everyone!

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# Time loss due to data hassle!

	Hours	Hours x3	Cost
			1 dr, 2 nurses = 1064 SEK/hr
Per day	0,5	1,5	1596,00
Per week	2,5	7,5	7980,00
Per month	11,25	33,75	35856,00
Per year	113	339	360696,00

For **three persons** working fulltime 0,5 hrs a day sums up to **8,4 weeks** a year or almost **361 000 SEK (38 590 EUR or 43 640 USD)** a year.

**The real cost is the double, 722 000 SEK if you count overhead and loss of income!**

# Two hours lost!

August 19, 2015

An invitation to log into the e-CRF, iMedidata RAVE, (which we already have certificates in and work with in other studies), to do the training for a new study, has arrived.

Training must be done before access according to the sponsor. Training is done and a quiz with irrelevant questions follow. (We on site are not interested to learn how the data management works and what the different icons are called. We want to learn the function.) I pass the quiz, but cannot print the certificate.

I try to access the iMedidata Rave without certificate for this study but to get access I need a PIN and Access code that I don't have.

I try the protocol name, etc. without result. I call the monitor, no answer, leave message on answering machine.

Trying to mail iMedidata on an automatic address by tapping a help-link on the page. I get the ERROR MESSAGE, (see next slide).

Then I try to call iMedidata in the United States. Answering machine. Left a message  
Now, two hours has passed and I give up !!

After another two hours yet no feedback from those I left the message on the answering machine.

## ERROR MESSAGE

Posted: August 19, 2015 11:49

Subject: Undeliverable :: certification

admin.medidata.ch rejected your message to the following email addresses:

certification@medidata.com (certification@medidata.com)

Unable to deliver the message because the recipient's e-mail system reported the following error: 550 No such domain at this location. There may be a temporary problem with their e-mail system. Try sending the message again. If the problem persists, contact the recipient in some other way (eg by telephone) and ask that they contact their mail administrator about the problem. Show them the error described above, it becomes easier for them to diagnose the problem.

For email administrators

This error is returned by the recipient's e-mail system, but it does not contain a valid, specific extended SMTP status code, which makes it difficult to assess exactly what the problem is. Carefully check the error reported by the recipient's e-mail system to help diagnose and troubleshoot the problem. Only the recipient's e-mail administrator can fix this.

admin.medidata.ch gave this error:

**No such domain at this location**

# Common issues

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Invitations by email to trainings or urge to read safety reports not specifying what study it refers to.

Different systems goes with different web –readers.

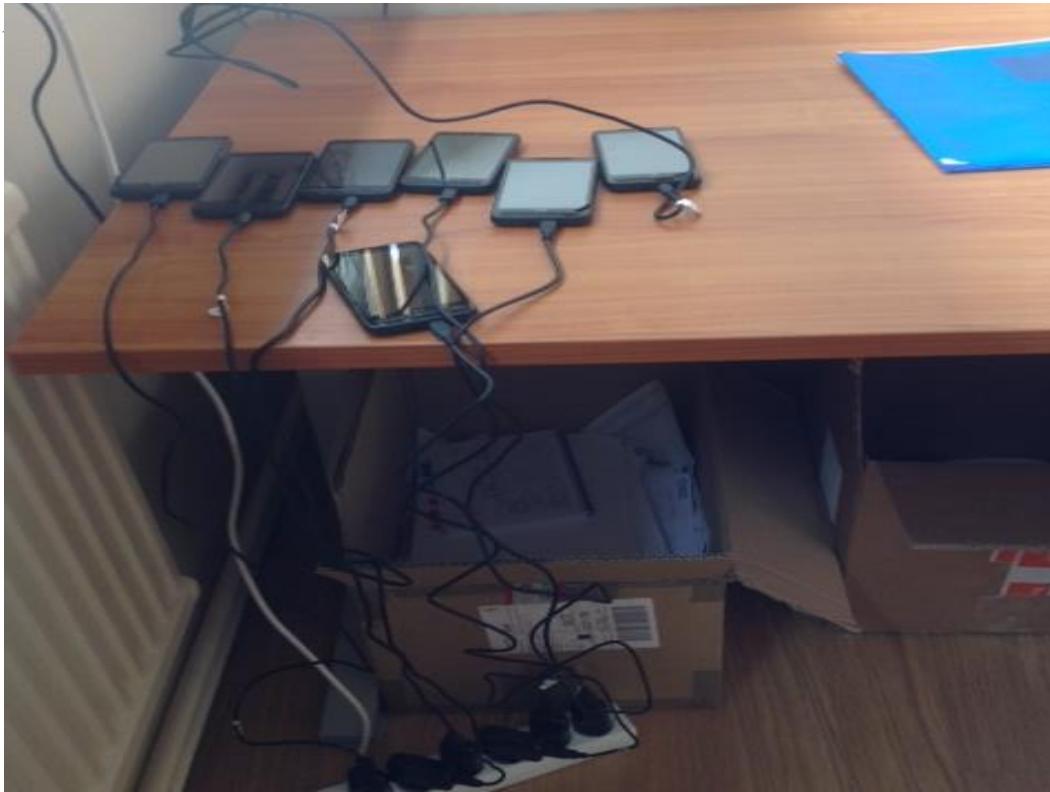
Migrations of databases – causes big trouble – not only for us I

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Queries two years after study visits – Not acceptable.

# Logpads

**E-diaries should facilitate studyparticipation both for us and for the studyparticipants! Not hinder it!**



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# Issues with electronic systems

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Loss of time

Loss of tempo

Loss of quality

Loss of work satisfaction

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# Issues with electronic systems

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**WE ARE NOT IT-TECHNICHIANs!!**

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# Take home messages 1

1. Construct e-CRF system where I as Investigator have control over my own data so that I can be sure of fulfilling my obligations according to regulations!

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2. **One headportal** and within this access to all of that companies studies that you are involved in and within each study access to **all** study-related systems. With **one password!** Or why not use a passwordgenerator that gives us a password valid for 30 sek.

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3. **Accept trainings and certificates from other sponsors.**

# Take home messages 2

4. Be sure of that all electronic equipment and systems have been properly tested and proven to work **before** they are implemented in real clinical trials.
5. Be sure that all electronic equipment is userfriendly. Especially patient-diaries.
6. Be sure of that systems from different vendors are compatible before the study starts!!

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7. Don't start a study or have an IM without all equipment in place.

# Take home messages 3

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8. Don't load over work on us, previously handled by data management, without giving us **adequate payment** for this job!

9. Deliver queries in direct connection with performed visits. Not two years later!!

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10. It must become easier to conduct clinical trials relating to electronic systems - otherwise you will not be able to find sites who wants to work with this in the future!

Pottholzt andra funderingar om...!  
...FULLÄNDAD COLOSKOPIUNDERSÖKNING

VAD HAR JAG FÖR FEL, DOKTORN?

HALSFLUSS!



I'TS ALL ABOUT PERSPECTIVE!

PATIENT: WHAT'S WRONG WITH ME DOC? DOCTOR: YOU'VE GOT TONSILLITIS!

22 SEPT 2015

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Please look at things from our  
perspective.  
Thank you!

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