An Introduction to Medical Devices Connectivity - The St George’s Experience

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NHS Foundation Trust

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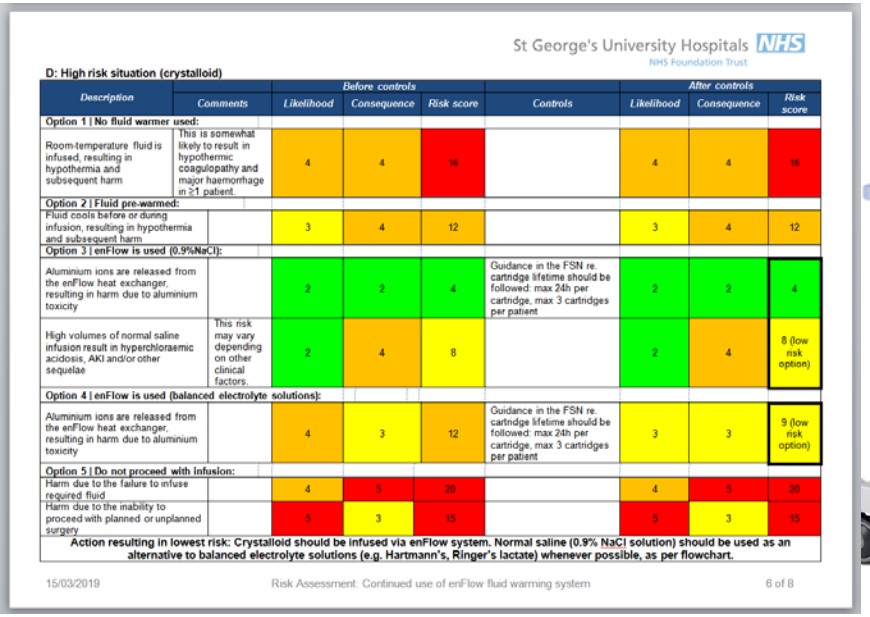
What are bioengineers good at?

High level

Low level



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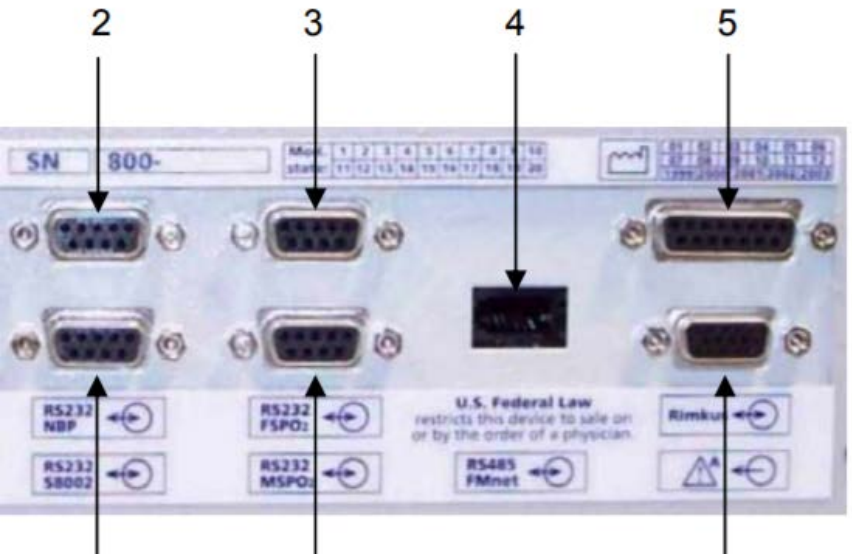
D: High risk situation (crystalloid)

Description	Comments	Before controls: Likelihood	Consequence	Risk score	Controls	After controls: Likelihood	Consequence	Risk score
Option 1 | No fluid warmer used:								
Room-temperature fluid is infused, resulting in hypothermia and subsequent harm	This is somewhat likely to result in hypothermic coagulopathy and major haemorrhage in ≥1 patient.	4	4	16		4	4	16
Option 2 | Fluid pre-warmed:								
Fluid cools before or during infusion, resulting in hypothermia and subsequent harm		3	4	12		3	4	12
Option 3 | enFlow is used (0.9%NaCl):								
Aluminium ions are released from the enFlow heat exchanger, resulting in harm due to aluminium toxicity		2	2	4	Guidance in the FSN re. cartridge lifetime should be followed: max 24h per cartridge, max 3 cartridges per patient	2	2	4
High volumes of normal saline infusion result in hyperchloraemic acidosis, AKI and/or other sequelae	This risk may vary depending on other clinical factors.	2	4	8		2	4	8 (low risk option)
Option 4 | enFlow is used (balanced electrolyte solutions):								
Aluminium ions are released from the enFlow heat exchanger, resulting in harm due to aluminium toxicity		4	3	12	Guidance in the FSN re. cartridge lifetime should be followed: max 24h per cartridge, max 3 cartridges per patient	3	3	9 (low risk option)
Option 5 | Do not proceed with infusion:								
Harm due to the failure to infuse required fluid		4	5	20		4	5	20
Harm due to the inability to proceed with planned or unplanned surgery		5	3	15		5	3	15

Action resulting in lowest risk: Crystalloid should be infused via enFlow system. Normal saline (0.9% NaCl solution) should be used as an alternative to balanced electrolyte solutions (e.g. Hartmann's, Ringer's lactate) whenever possible, as per flowchart.

15/03/2019 Risk Assessment: Continued use of enFlow fluid warming system 6 of 8

Clinical connectivity for engineers



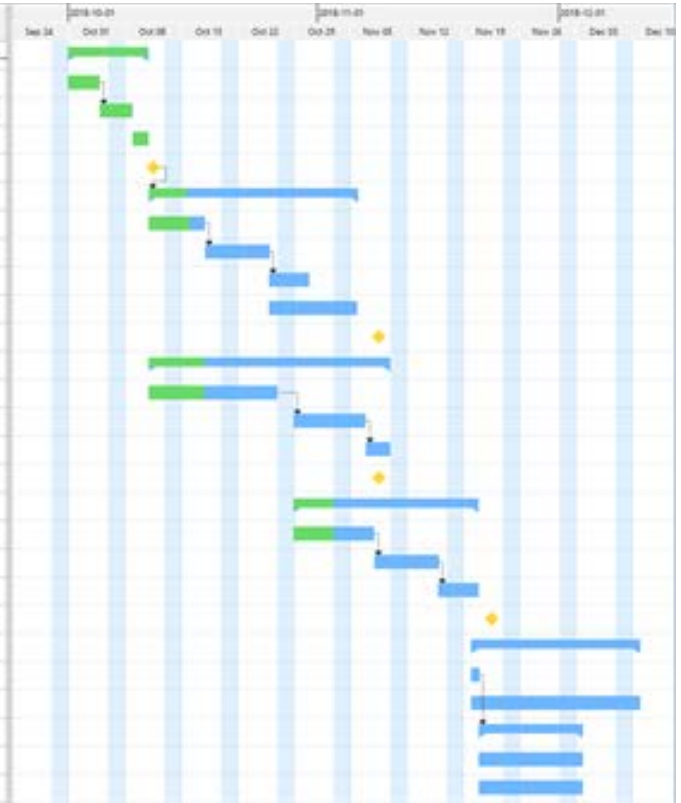
2 RS232 connector
9-way D-type socket (reserved for future use)

- ✓Is the medical device broken? I can fix it.
- ✓Do you need a cable? I can make a cable.
- ✓Are you seeing data at your end yet?
- ✓That will be 23p for the solder please.

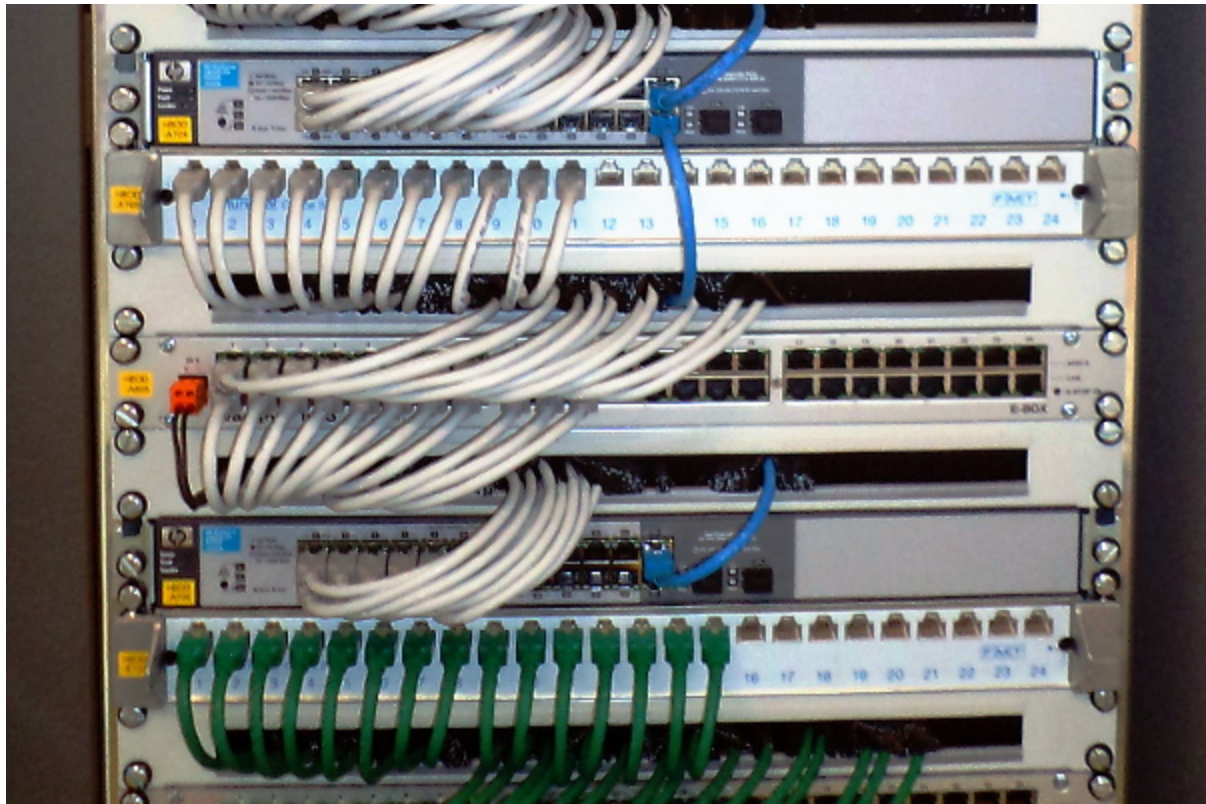
What are IT departments good at?

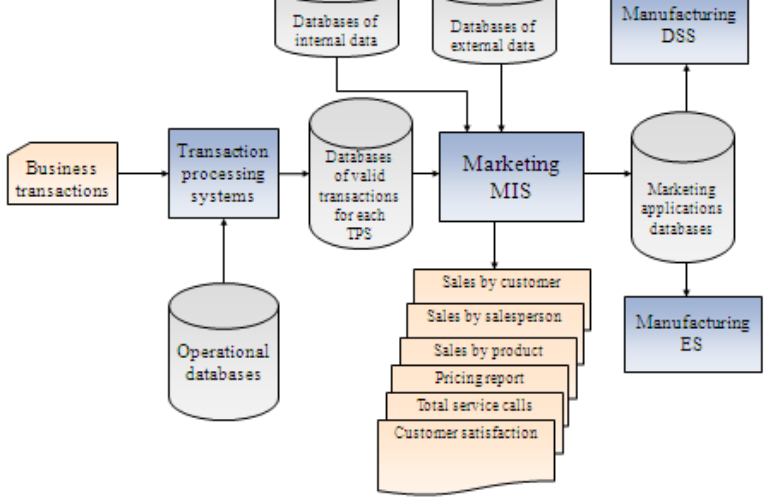
High level

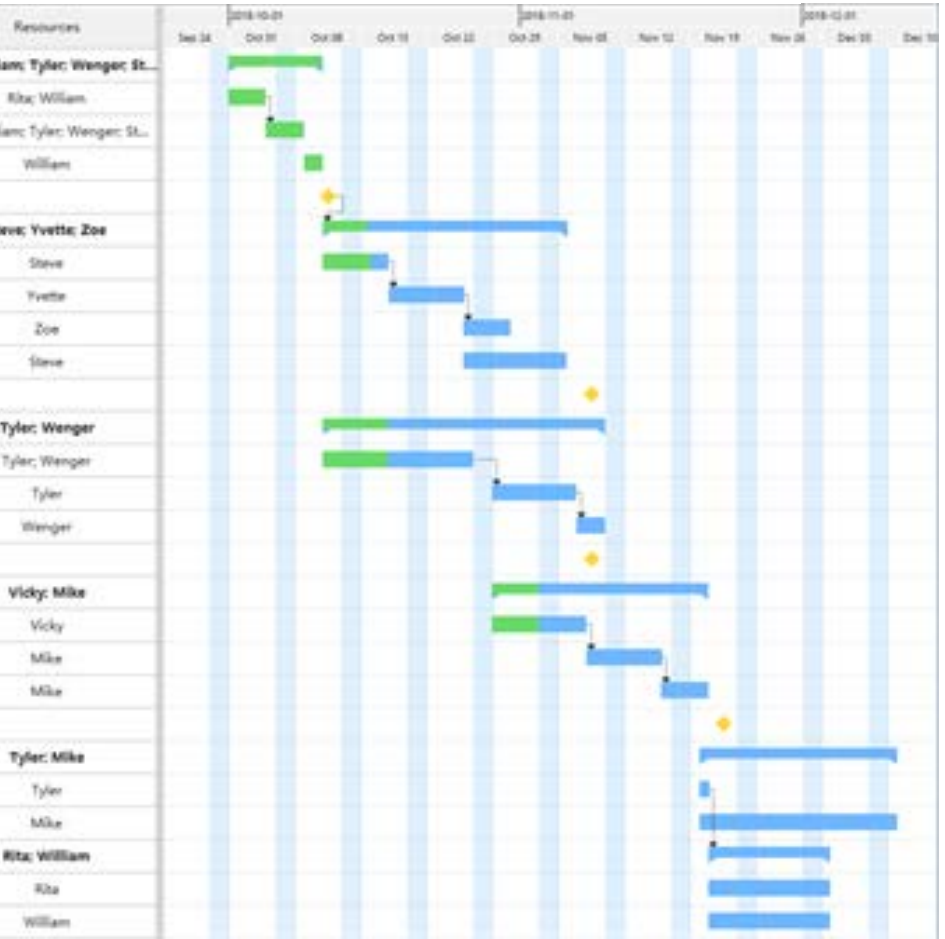
	Start	Finish	Duration	Progress	Priority	Resources
	2018-10-01 08:00	**2018-10-10 16:00**	**8 d**	**98.9%**	1	**Rita; William; Tyler; Wenger; St...**
	2018-10-01 08:00	2018-10-04 16:00	4 d	100%	1	Rita; William
ders	2018-10-05 08:00	2018-10-08 16:00	2 d	95.5%	3	Rita; William; Tyler; Wenger; St...
	2018-10-09 08:00	2018-10-10 16:00	2 d	100%	3	William
	2018-10-10 08:00	2018-10-10 16:00	1 d	0%	1	
	2018-10-11 08:00	**2018-11-05 16:00**	**18 d**	**14.9%**	2	**Steve; Yvette; Zoe**
	2018-10-11 08:00	2018-10-17 16:00	5 d	62.4%	1	Steve
	2018-10-18 08:00	2018-10-25 16:00	6 d	0%	2	Yvette
	2018-10-26 08:00	2018-10-30 16:00	3 d	0%	4	Zoe
	2018-10-26 08:00	2018-11-05 16:00	7 d	0%	2	Steve
	2018-11-05 08:00	2018-11-05 16:00	1 d	0%	2	
	2018-10-11 08:00	**2018-11-09 16:00**	**22 d**	**22.5%**	3	**Tyler; Wenger**
	2018-10-11 08:00	2018-10-26 16:00	12 d	41.2%	1	Tyler; Wenger
	2018-10-29 08:00	2018-11-06 16:00	7 d	0%	1	Tyler
	2018-11-07 08:00	2018-11-08 16:00	3 d	0%	2	Wenger
	2018-11-09 08:00	2018-11-09 16:00	1 d	0%	3	
	2018-10-29 08:00	**2018-11-20 16:00**	**17 d**	**29.4%**	4	**Vicky; Mike**
	2018-10-29 08:00	2018-11-07 16:00	8 d	62.5%	3	Vicky
	2018-11-08 08:00	2018-11-15 16:00	6 d	0%	4	Mike
	2018-11-16 08:00	2018-11-20 16:00	3 d	0%	1	Mike
	2018-11-20 08:00	2018-11-20 16:00	1 d	0%	3	
	2018-11-20 08:00	**2018-12-10 16:00**	**15 d**	**0%**	1	**Tyler; Mike**
	2018-11-20 08:00	2018-11-20 16:00	1 d	0%	5	Tyler
	2018-11-20 08:00	2018-12-10 16:00	15 d	0%	4	Mike
	2018-11-21 08:00	**2018-12-03 16:00**	**9 d**	**0%**	2	**Rita; William**
	2018-11-21 08:00	2018-12-03 16:00	9 d	0%	3	Rita
	2018-11-21 08:00	2018-12-03 16:00	9 d	0%	1	William



Low level



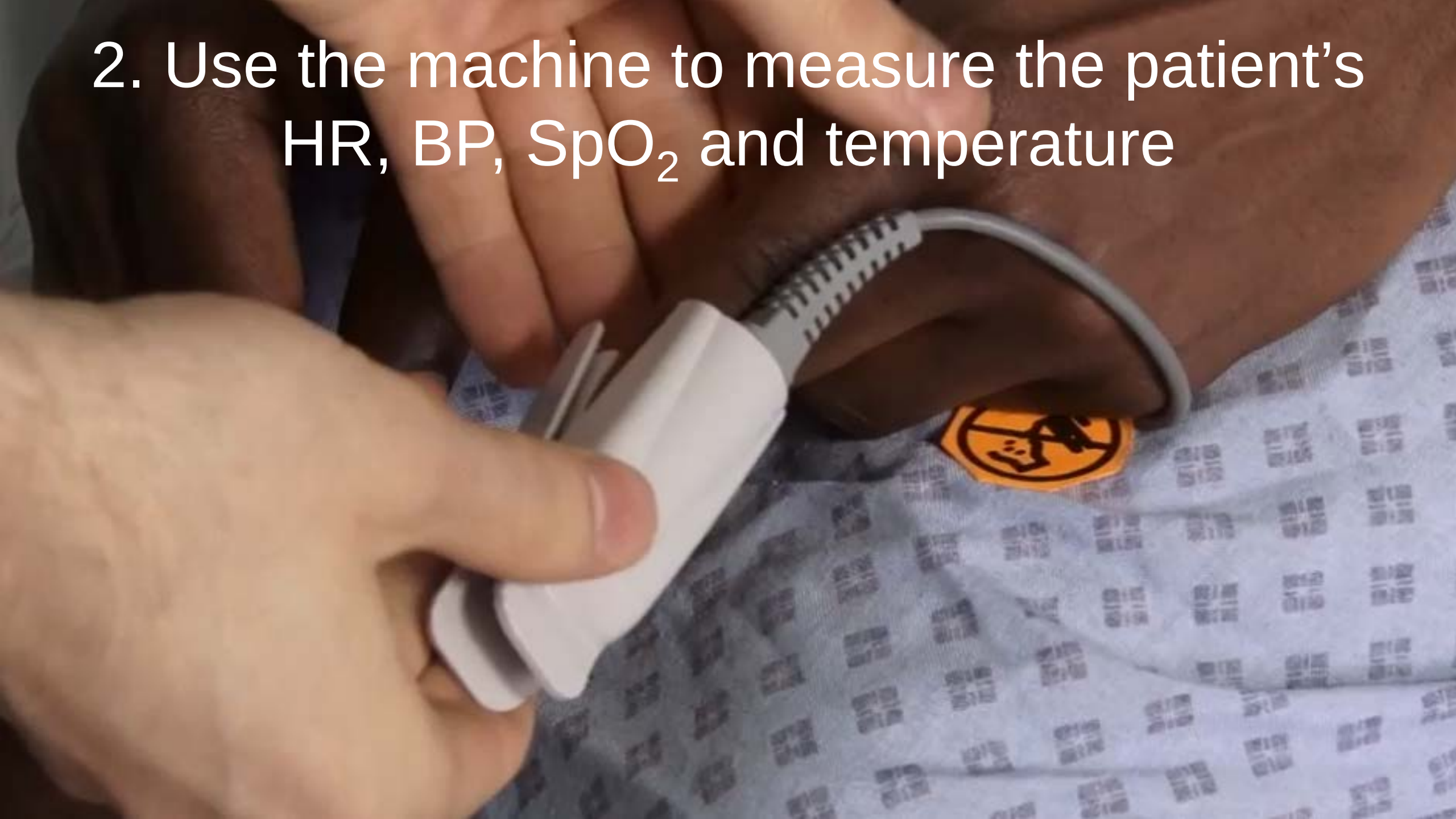




Clinical connectivity for IT teams

- ✓ The project will be lean, Six Sigma, agile, kaizen, just-in-time and our Black Belt scrum masters are at the ready
- ✓Limited resources until project funding comes in
- ✓A culture of robust testing and controlled deployments
- ✓Clinical environment is unfamiliar so we ask for help with that

1. Scan the patient’s wristband



2. Use the machine to measure the patient's HR, BP, SpO_2 and temperature

3. Enter the remaining observations directly onto the screen of the Connex VSM

4. Send the whole set of observations to the electronic patient record

Value

Complement

the delivery of major projects

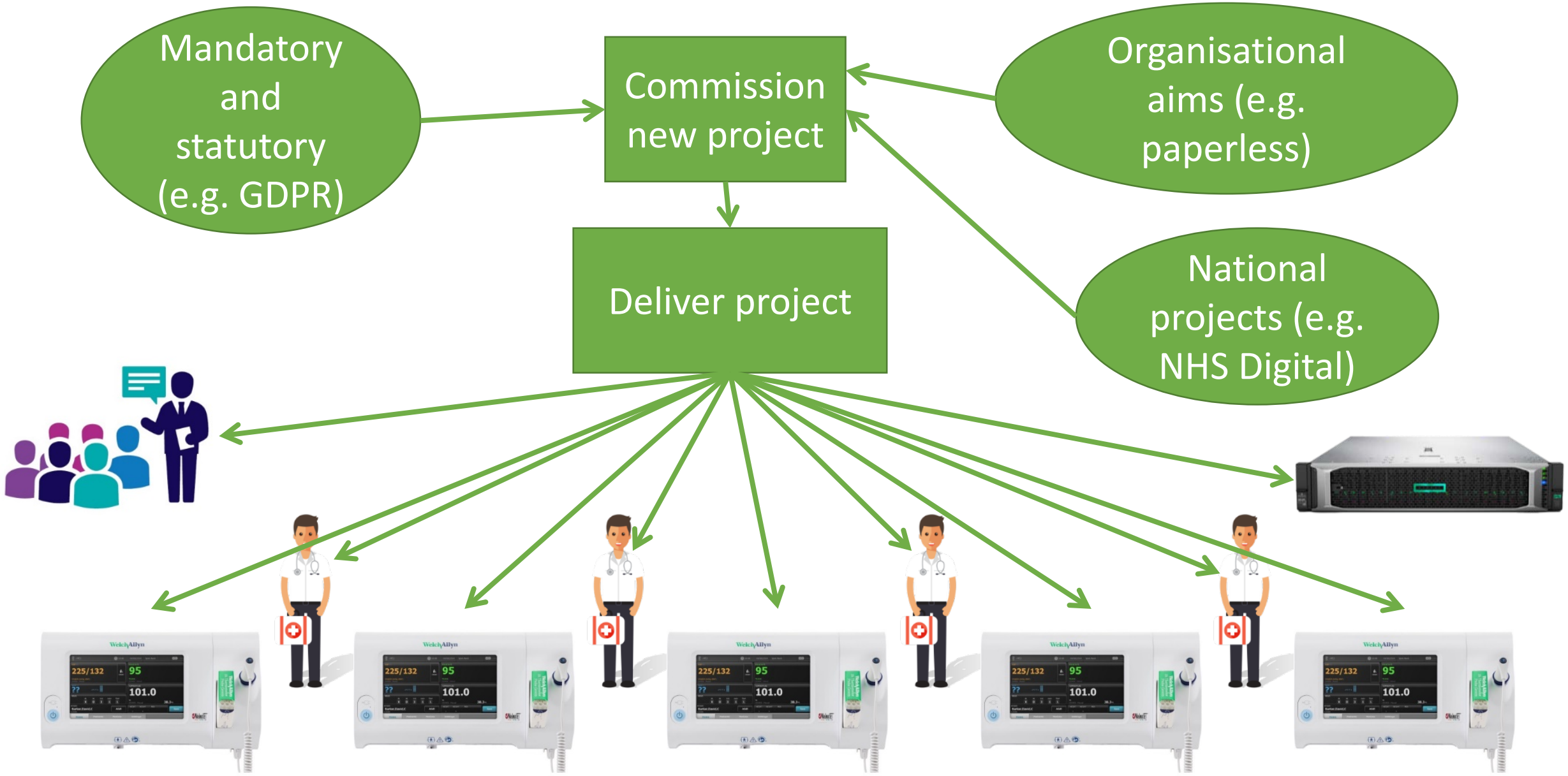
Enhance

clinical provision by delivering smaller improvement projects

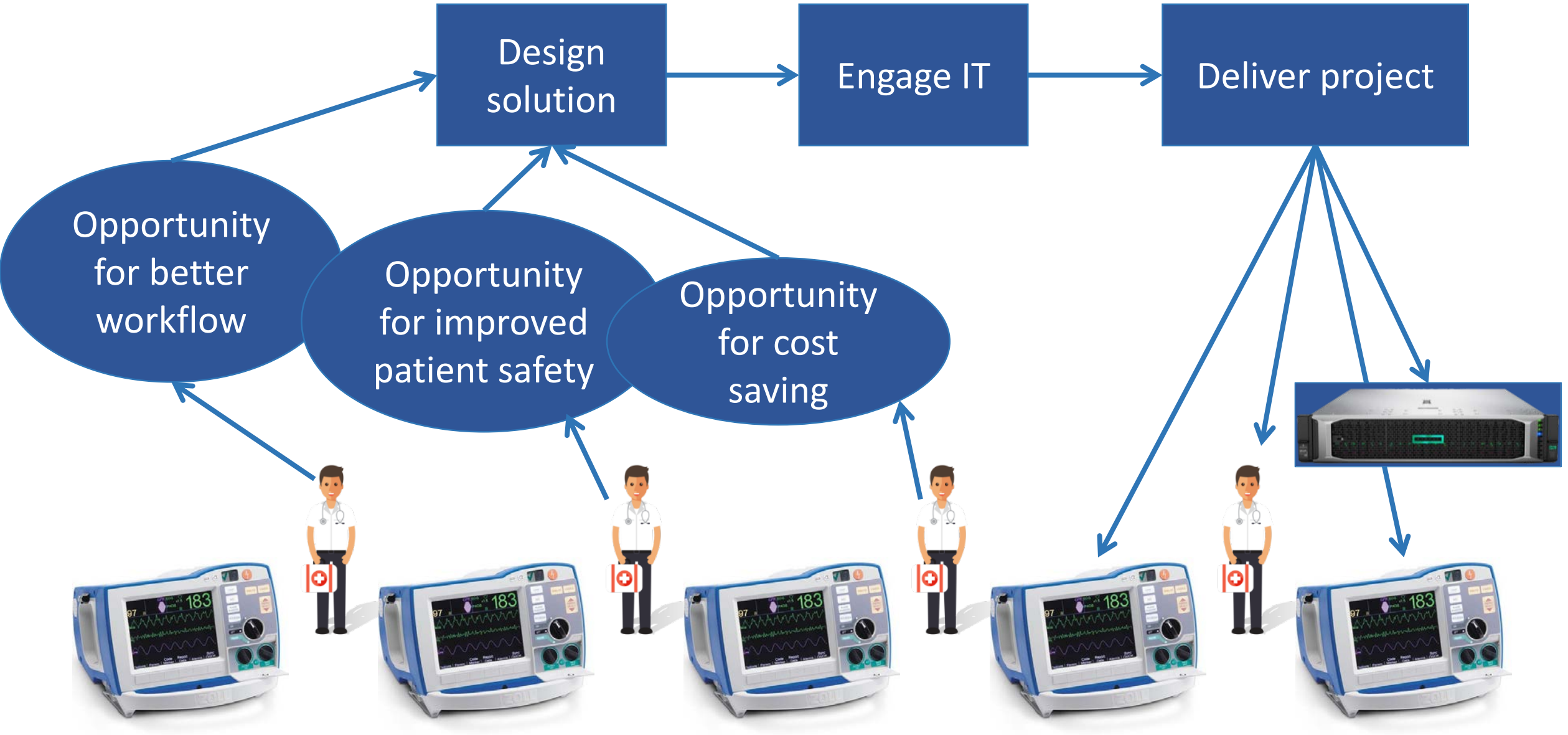
Act as expert

for connected medical equipment and software

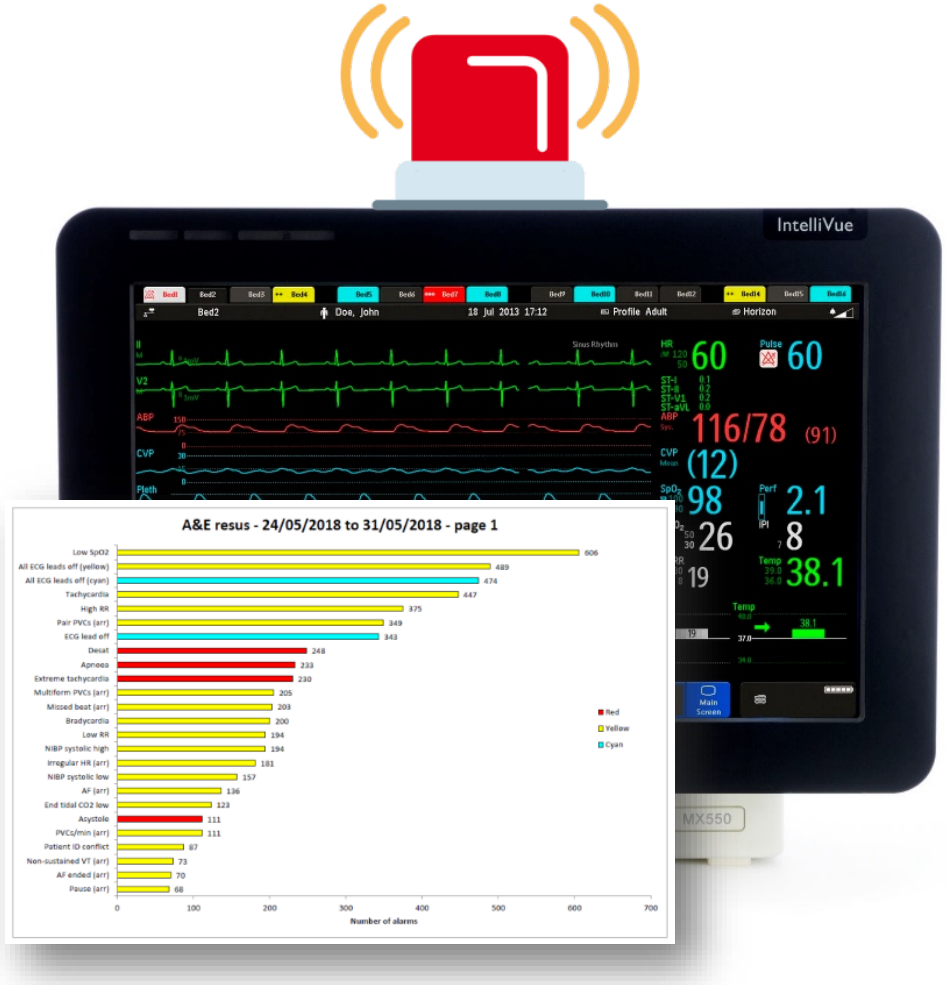
Conventional approach to information projects



Bottom-up approach



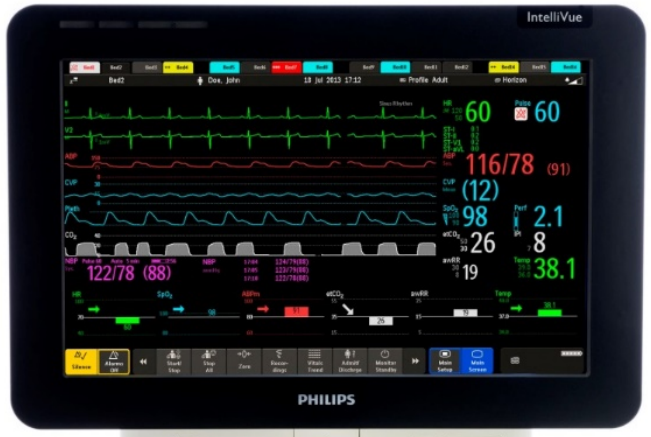
Bottom-up: no job too small



IT hardware

??????????????

Medical device



✓ Approved model
✓ Up-to-date, secure OS
✓ Sits on our domain
✓ Gets regular updates

Old, insecure OS
No AV
No updates

You can't change those

✓ Best device for the job
✓ Carefully maintained
✓ All risks managed

Looks like a PC to me…

Don't touch. It's a medical device!

Then turn it off!

IT

Engineering

Person specification

- A broad understanding of medical devices
- Computing skills: hardware, virtualisation, networking
- Knowledge of cybersecurity and data governance
- HL7 and DICOM
- Basic coding and scripting skills
- A practical approach to project management
- Confidence?

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THE DANGERS OF SHADOW IT

Shadow IT can be a force for good, driving innovation and enabling business agility. But unregulated IT projects can be expensive and dangerous.

We can all get along

Shadow IT…	Medical devices connectivity must…
is cyber-insecure	follow best cybersecurity practice where possible Risk-assess and control if necessary
disregard data governance	take responsibility for all aspects of data governance, with DPIAs approved at organisational level
contaminate networks and interfaces	work with IT to ensure networking resources are allocated properly
without regard to proper project management	run projects robustly and transparently, with excellent documentation

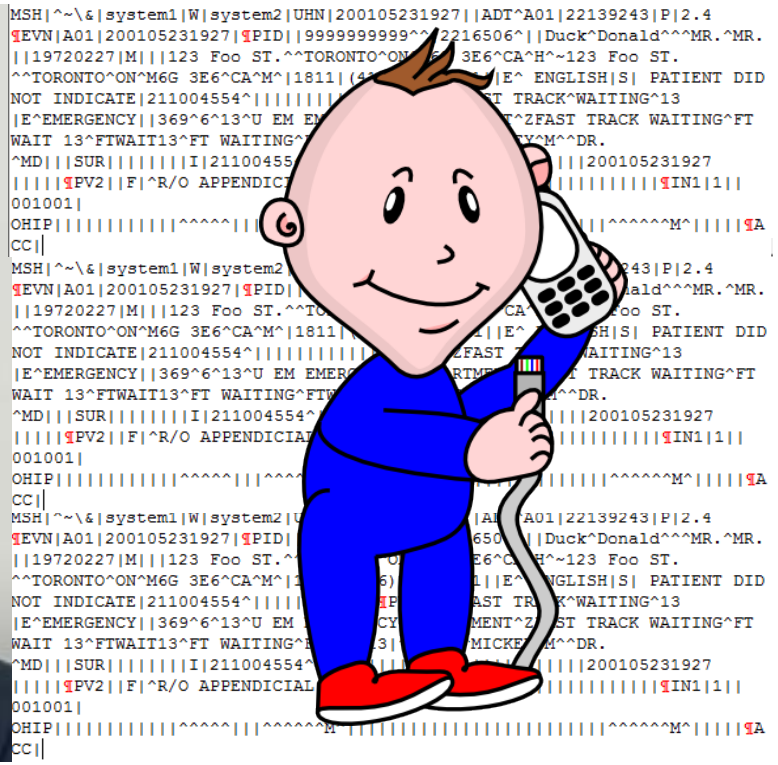
What we've done so far

- Received, triaged and working on over 50 new project requests per year
- Support for several major clinical systems (including Philips IntelliVue monitoring) and their interfaces
- Assisted research projects with clinical data collection
- Developed complex applications to support medical device training

Future work

- Supporting medical equipment management with innovative solutions (RTLS; GS1)
- Site-wide dashboarding
- Forensic clinical data

Connectivity team 2019



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