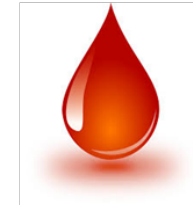


Patient Centric Sampling – What is it, where are we up to and where might it be leading us?

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Micro-volumes
($\leq 100 \mu$ L)

This presentation is **NOT** about microsampling!!!

What is the most important factor for quantitative bioanalysis?

The sample....



What is the most important factor for quantitative bioanalysis?



....sample
processing, storage
& shipping.....

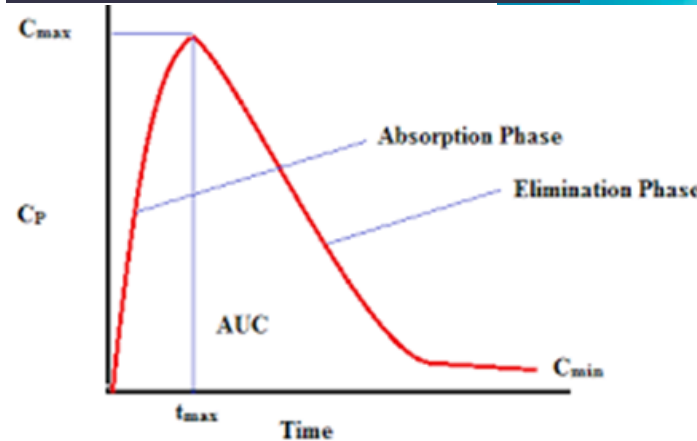
What is the most important factor for quantitative bioanalysis?

....sample analysis....



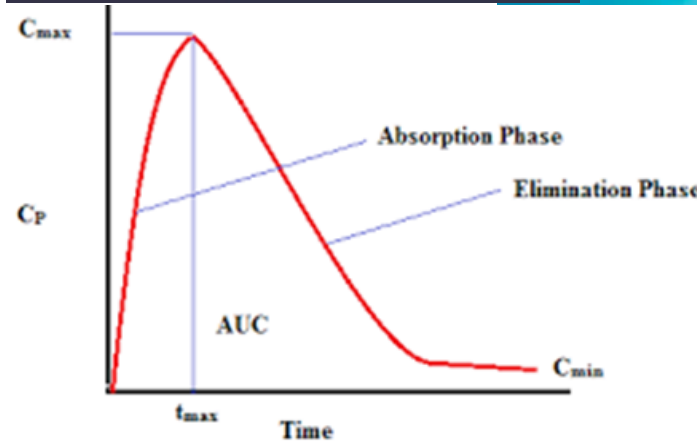
What is the most important factor for quantitative bioanalysis?

....PK data....



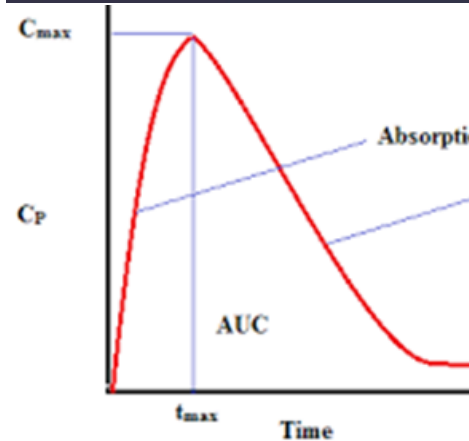
What is the most important factor for quantitative bioanalysis?

....cost....



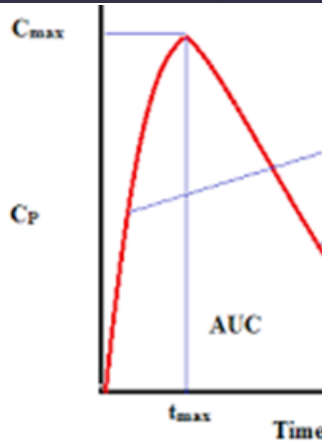
What is the most important factor for quantitative bioanalysis?

....regulations....



What is the most important factor for quantitative bioanalysis?

....or is it?





We are at the cusp of a new way of thinking about human sampling for quantitative bioanalysis

With the **PATIENT** being at the centre of our considerations
(while collecting a high quality sample)

Benefits of Patient Centric Sampling

Quality	Obtaining a high quality blood / plasma / serum sample for accurate quantitative determination of drugs, drug metabolites & endogenous molecules
Patient	Minimising the impact on the human patient / consumer • Optimising blood volume sampled • Minimising pain • Facilitating convenience
New Data	Generating concentration data in situations that are currently difficult, or impossible to work with

Moving Beyond Conventional Dried Blood Spot Sampling

- Overcoming the issues associated with
 - Blood hematocrit
 - Sample homogeneity
- Whilst
 - Delivering cost savings through home sampling and room temperature sample shipments
 - Facilitating self sampling
 - Integrating with systems for sample shipping / tracking and analysis



The puzzle is coming together

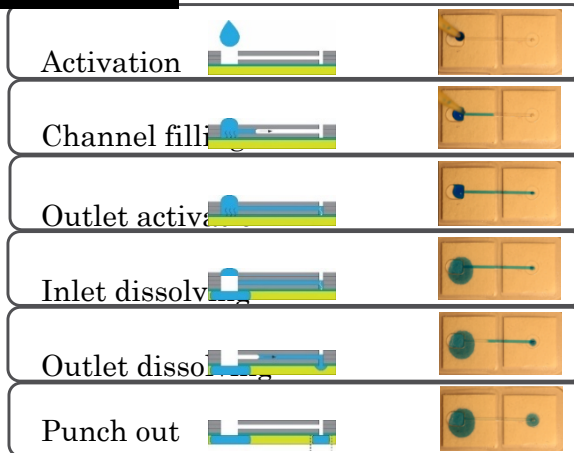
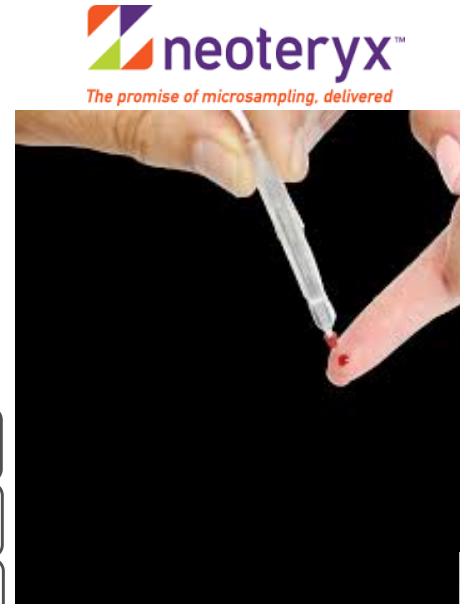


Patient Centric Technologies – Samplers*



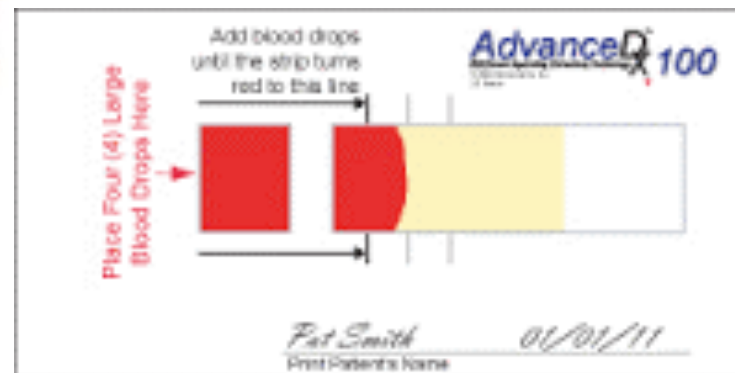
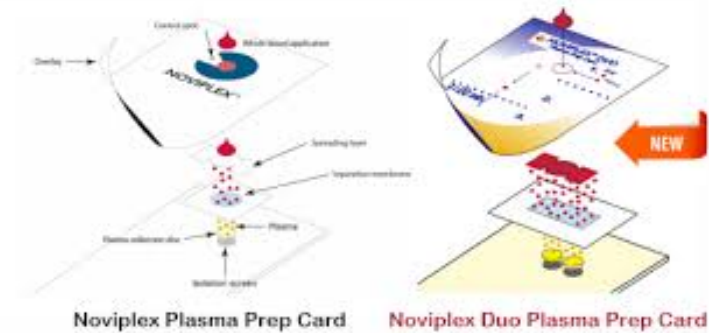
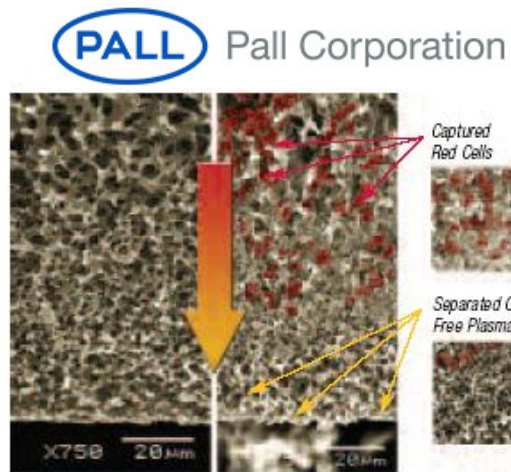
*Other technologies are available

Patient Centric Technologies – Blood Collection*



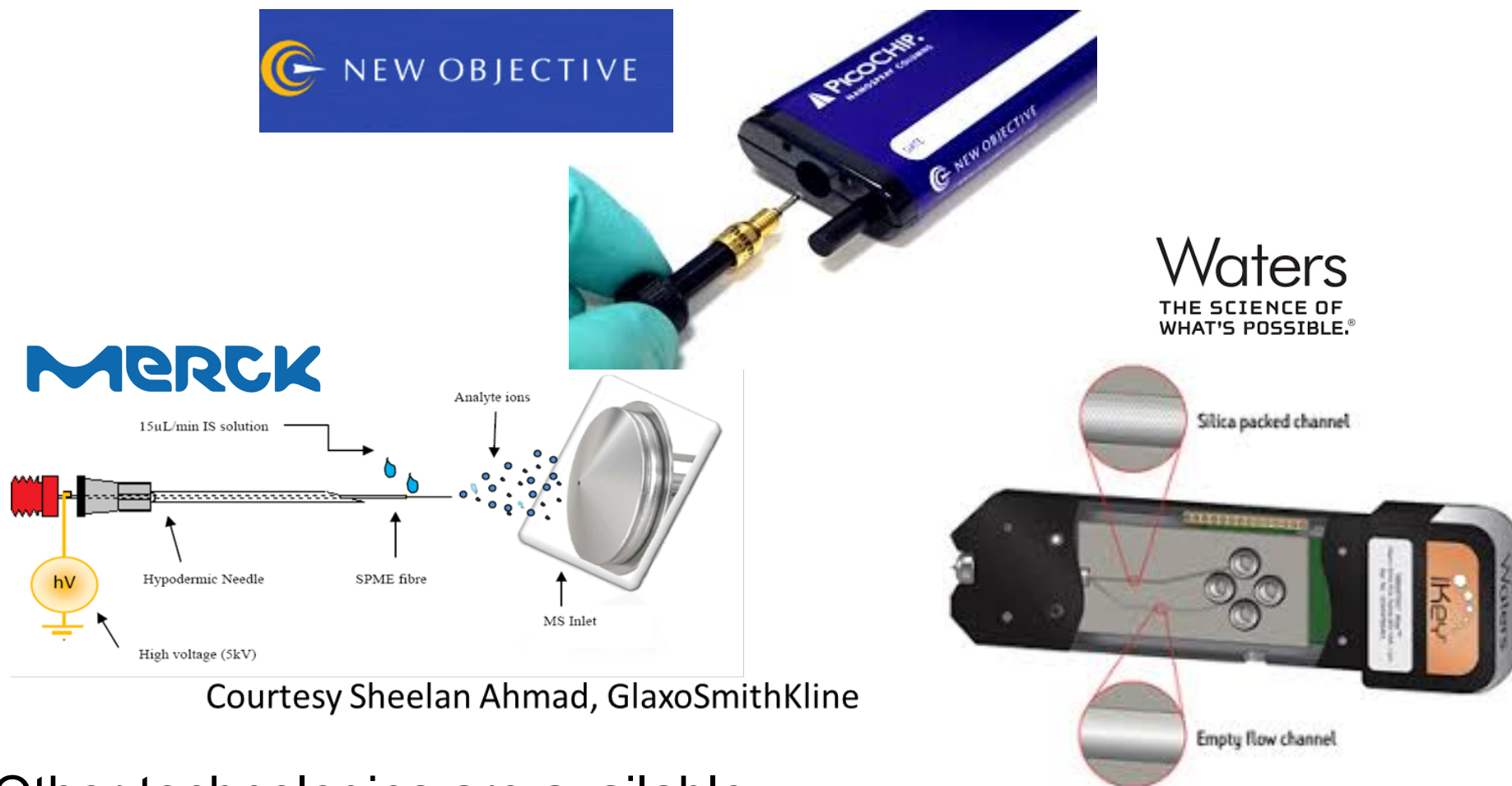
*Other technologies are available

Patient Centric Technologies – “Plasma” Collection*



*Other technologies are available

Patient Centric Technologies – Analysis*



Courtesy Sheelan Ahmad, GlaxoSmithKline

*Other technologies are available

So what does this enable us to do?

- Ability to generate exposure data where otherwise difficult
 - This is about more than standard PK sampling for current clinical trial designs
- Sampling in the home / pharmacy / local Doctor's office
 - Self sampling / assisted sampling
- Obtain 'new' information
 - Demonstration of patient compliance
 - Therapeutic drug monitoring – correct dose, correct drug
 - Obtaining data during a clinical episode
 - Application to popPK and trough sampling study designs
- Facilitating pediatric studies
- Sampling in geographically remote locations
- Sampling critically ill patients



Facilitating patient driven healthcare.....

- NB - these technologies all require a time stamp for sample collection

Home Sampling – Potential for Cost Savings

- If subjects no longer have to travel to a central clinic on study days where only PK samples are being collected

	Phase II	Phase III
Cost Saving	ca. €84K	ca. €280K

- Data is for an ‘average’ study defined as follows
 - Average number of patients = 300 for Phase II, 1000 for Phase III
 - Average number of sampling occasions per study where the only event is the collection of PK samples = 2 out of 5
 - Average subject expenses cost per visit to the clinic = €140
- The following are not included in the cost savings
 - 2-4 hours of subject time per visit
 - Cost of the home sampling kit
 - Subject training
 - Staff costs associated with collection of these samples at the clinic

Cost savings for TDM of renal transplant & hemato-oncology pediatric patients

Total societal savings

- 43% for hemato-oncology (€277 to €158 per blood draw)
- 61% for nephrology (€259 to €102 per blood draw)
 - Includes healthcare costs provision, patient related costs & costs related to loss of productivity of the caregiver

Healthcare only savings

- 7% for hemato-oncology
- 21% for nephrology



This is not about microsampling!!!

- It is about collecting.....
 - the appropriate sample.....
 - in a location that is most convenient for the patient
- This may be blood sample volumes of 10 μL , or it may be 250 μL



Potential Challenges

- Is the sample representative of the whole?
- Non-conventional sample format
 - Sample transfer
 - Storage
 - Analysis
 - Automation
- Additional validation steps
- Data acceptability
 - Regulators
- Reluctance to change!!!



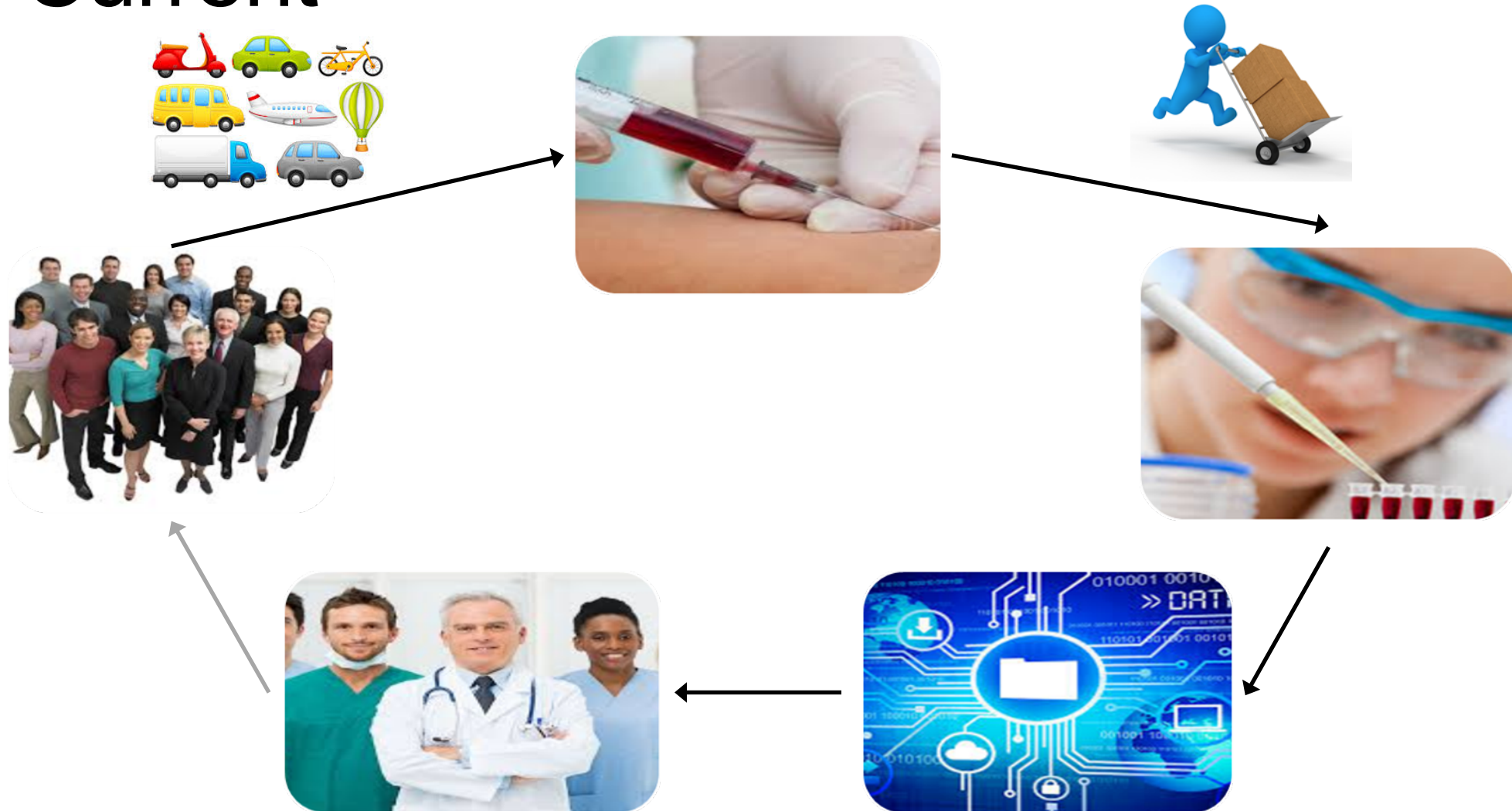


What does this mean for the bioanalytical laboratory?

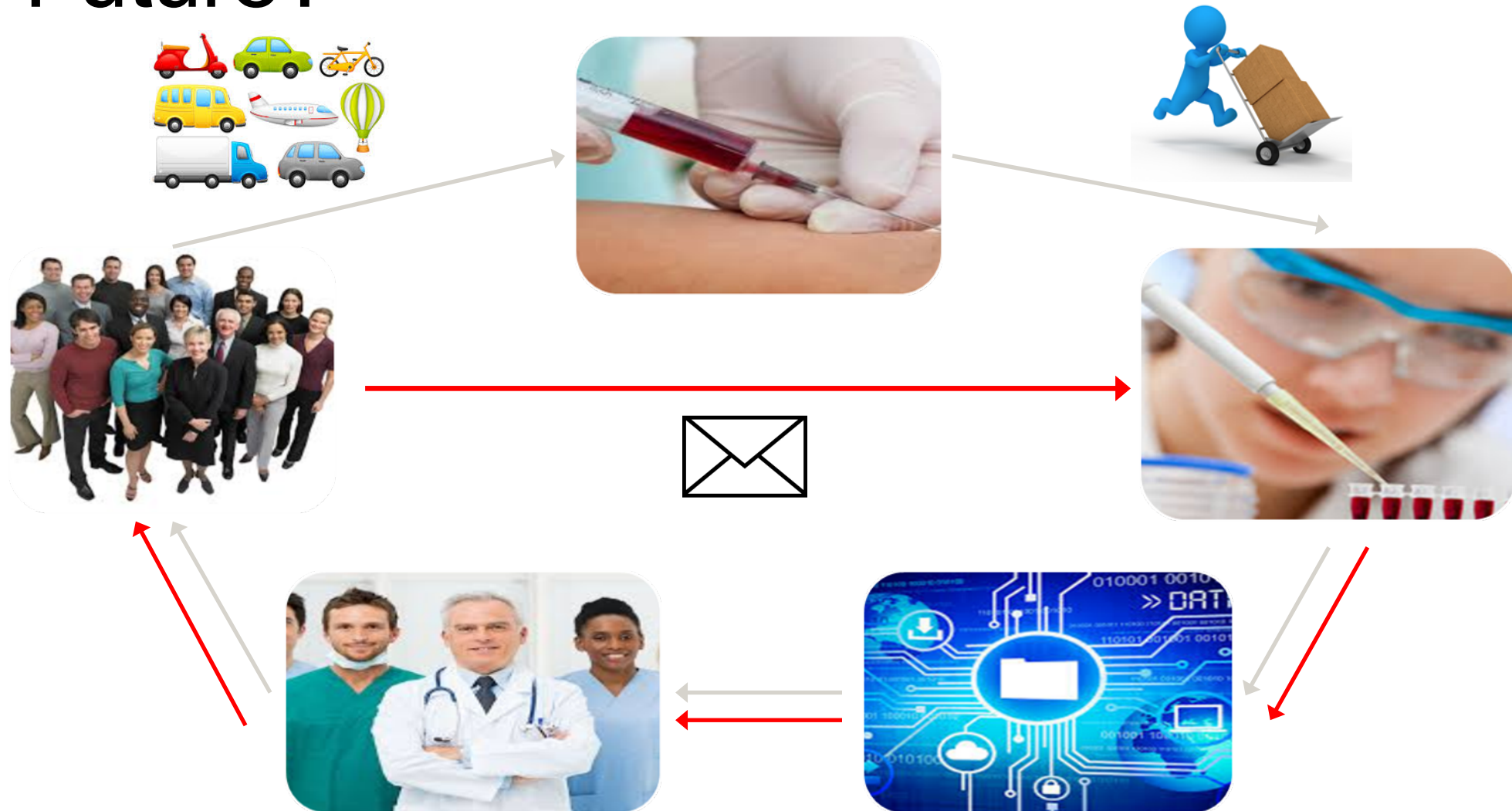
It depends on how you look at it!

Possible new paradigm?

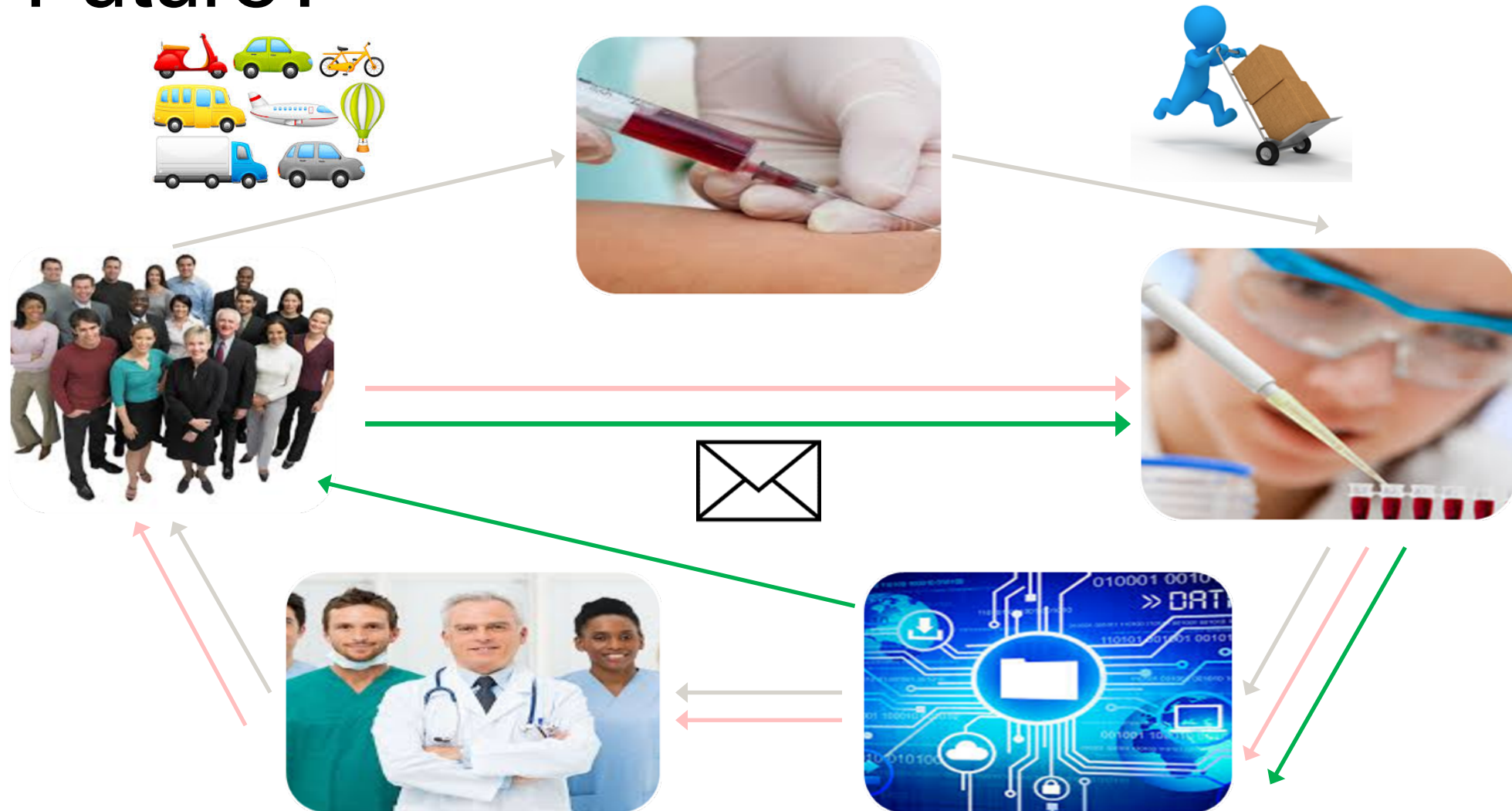
Current



Possible new paradigm? Future?



Possible new paradigm? Future?



Conclusions

- New blood sampling & analytical technologies are emerging
- This enables us to put the patient first
- It also enables us to collect data that has previously been difficult / impossible to obtain
- Change will not be straightforward!





Together we can do this!

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