dPharMaQC
Digitalization of Pharmaceutical Manufacturing Quality Control

www.fssg.se/synergy19

AstraZeneca

KARLSTAD UNIVERSITY

Agilent

Bio-Works

cytiva

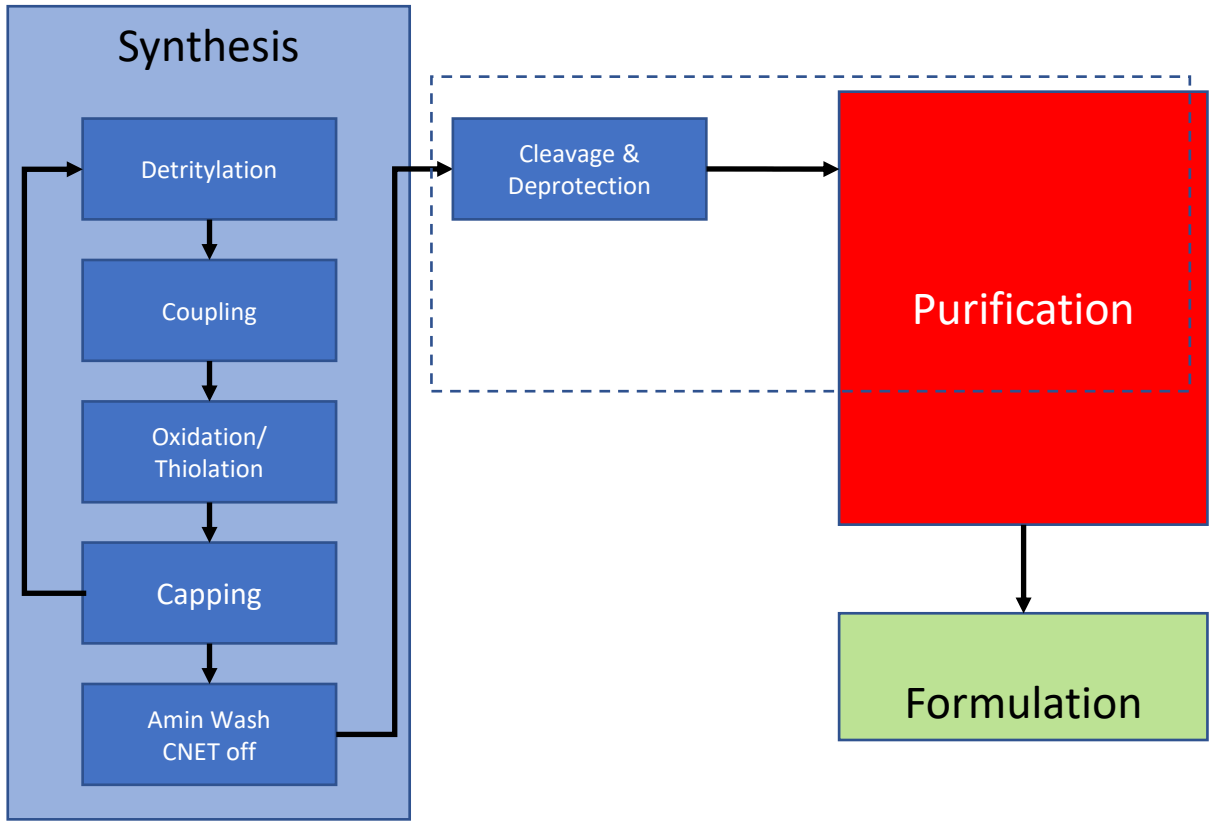
Background

- Most pharmaceutical shortages are mainly due to quality Issues.
- Reluctance to invest in quality management systems for mature products.
- Regulatory authorities and pharma/biopharma sector conservative → tedious and costly approval processes
- Future pharmaceuticals based on complex molecules → increased complexity of manufacturing processes and Quality Control (QC) methods
- Current situations related to COVID-19 further emphasized the importance of this work

Large-scale Oligonucleotides Manufacturing Process (LOMP)

Multistep manufacturing process with several process intermediates and high-quality demands on the final product,

- **Low yields and high costs**
- **Multiple sources of variability**
  For example, raw materials, process conditions caused by intrinsic variability in the technology used and human errors
- **Tight process operating window**

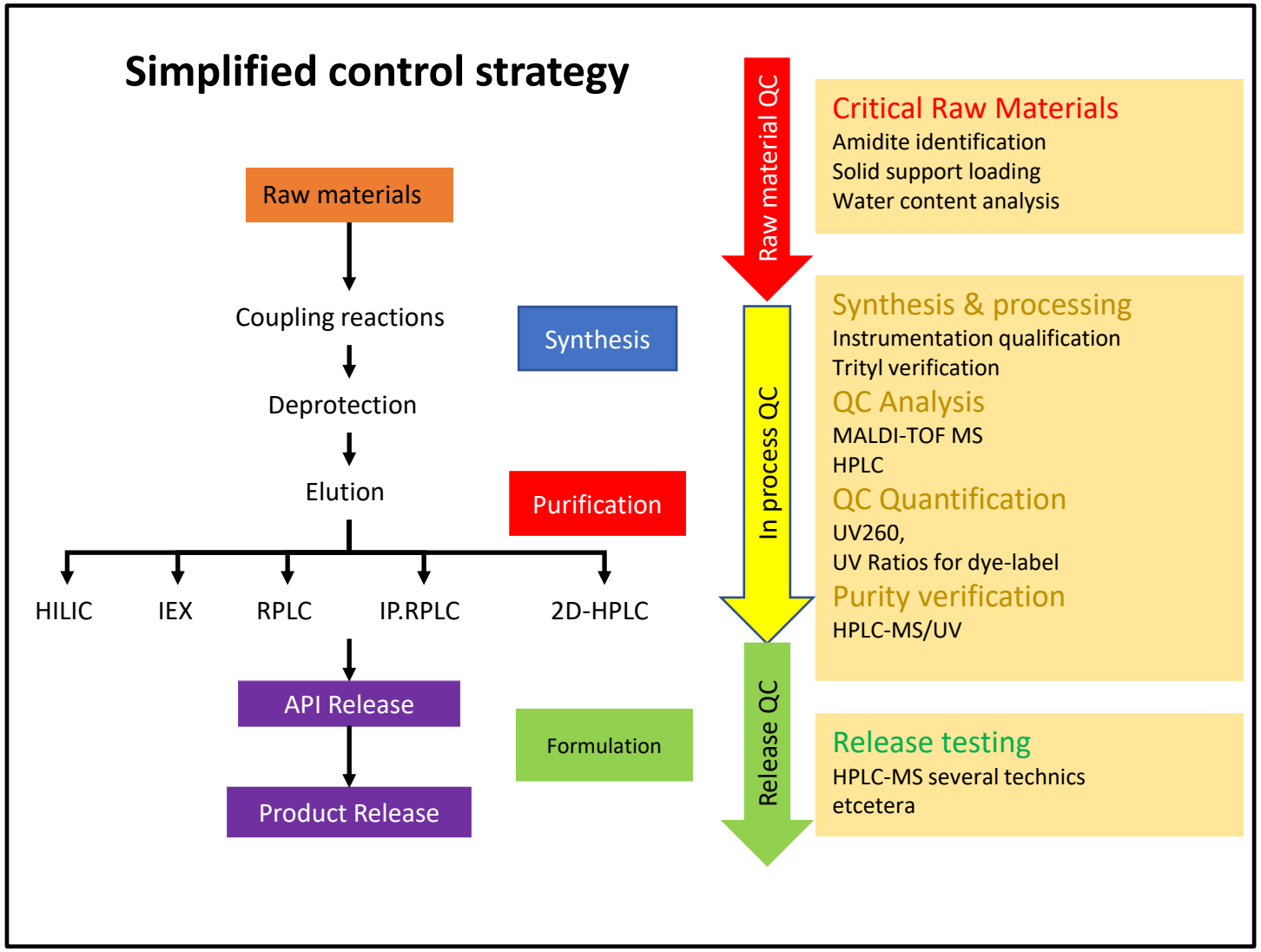


Current Control Strategy for LOMP

- **Raw material QC**
  Out of spec raw materials can lead to delays
- **In-process QC**
  Processes operated on the risk management principle (batch performed and release after QC results ready).
- **Release QC**
  Out of spec, leading to product quarantine and manufacturing investigation etc.

Currently, in-process data is not fully utilized in the release QC method. Linkages between process control and QC release are not fully established.

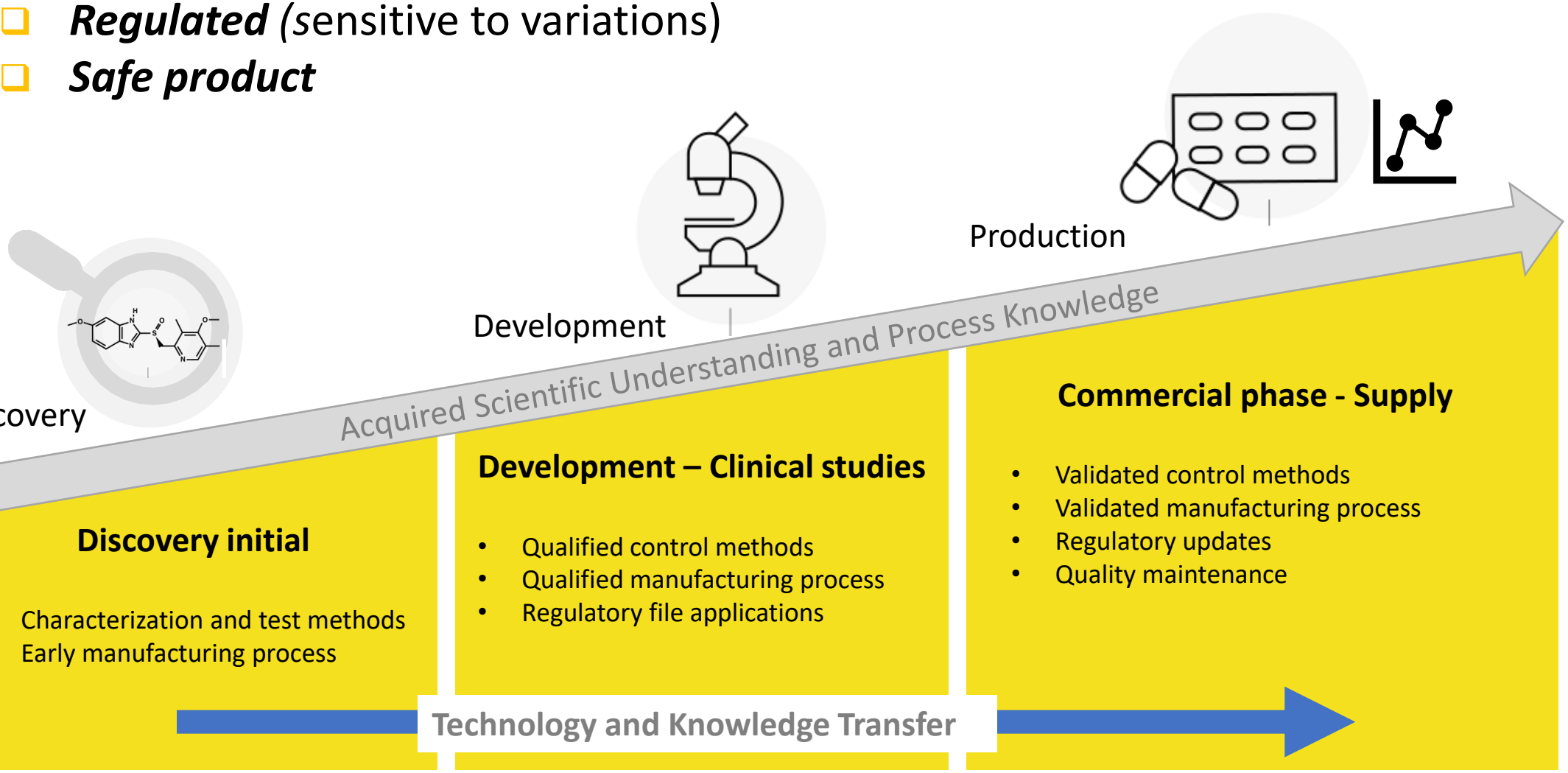
How can we improve the current control strategy?



Current Drug Development Process (QC Perspective)

- Long timelines
- High uncertainty
- ***Regulated*** *(sensitive to variations)*
- ***Safe product***

HIGH COST



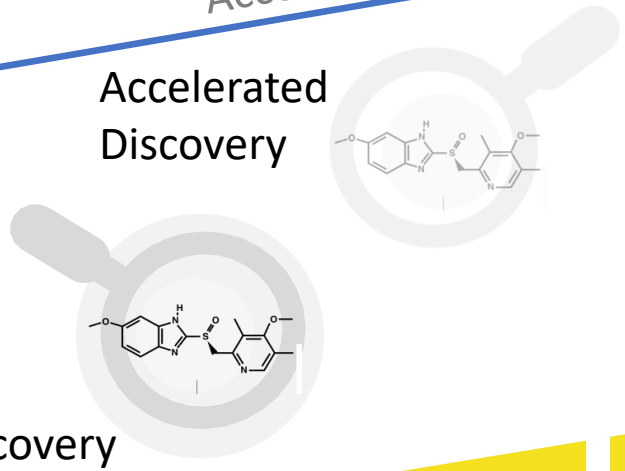
Future Drug Development Process (QC Perspective)

- Short timelines
- Low uncertainty
- ***Regulated*** *(robust)*
- ***Safe product***

LOW COST (> €20M savings)

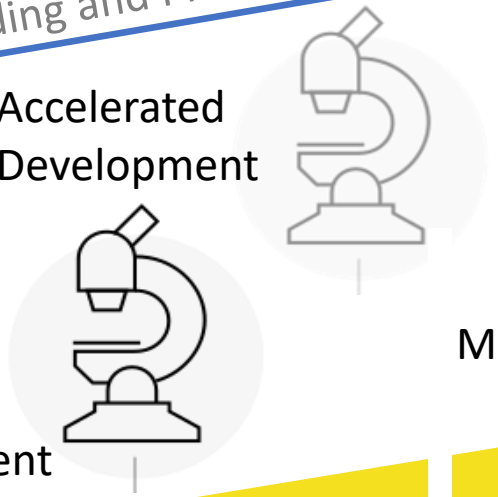
Accelerated Scientific Understanding and Process Knowledge through **Digitalization**

Accelerated Discovery



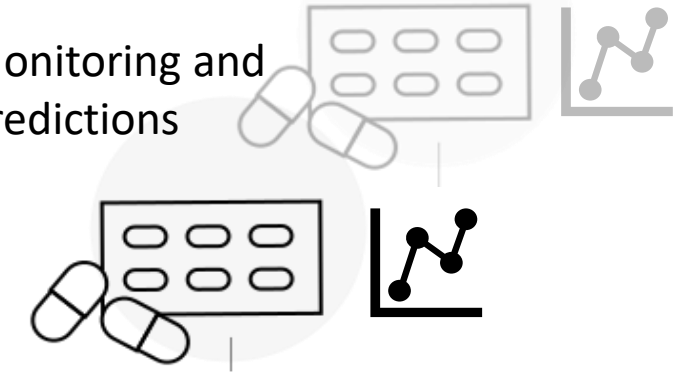
Discovery

Accelerated Development



Development

Monitoring and Predictions



Monitoring

Discovery initial

- Characterization and test methods
- Early manufacturing process

Development – Clinical studies

- Qualified control methods
- Qualified manufacturing process
- Regulatory file applications

Commercial phase - Supply

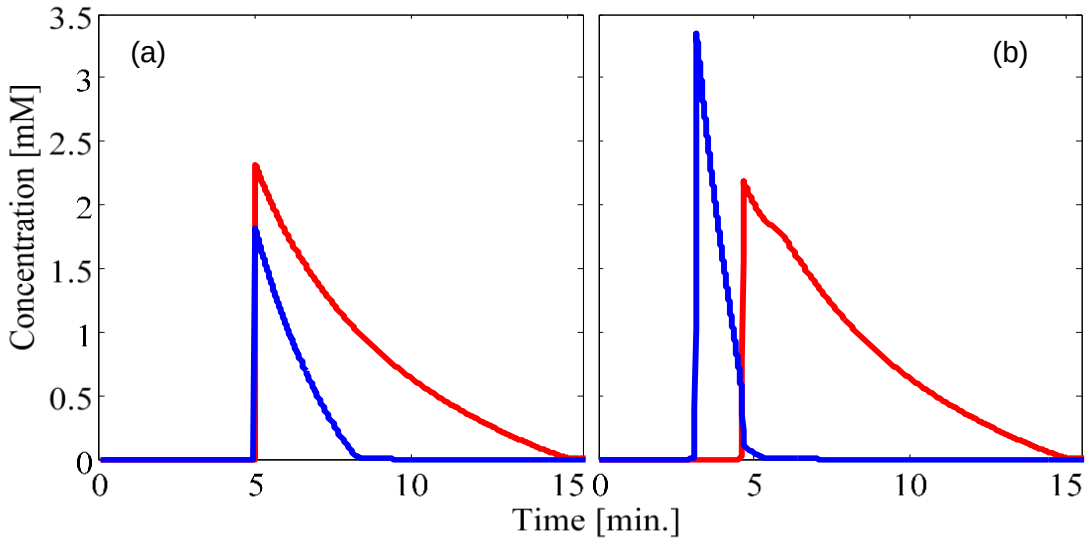
- Validated control methods
- Validated manufacturing process
- Regulatory updates
- Quality maintenance

Accelerated Technology and Knowledge Transfer

Project Core Question

How do we utilize modern digitalization techniques to improve quality control in pharmaceutical manufacturing?

Answering the core question will be collaborative effort between the industrial and academic partners, where each partner contributes with specific expertise and/or resources.



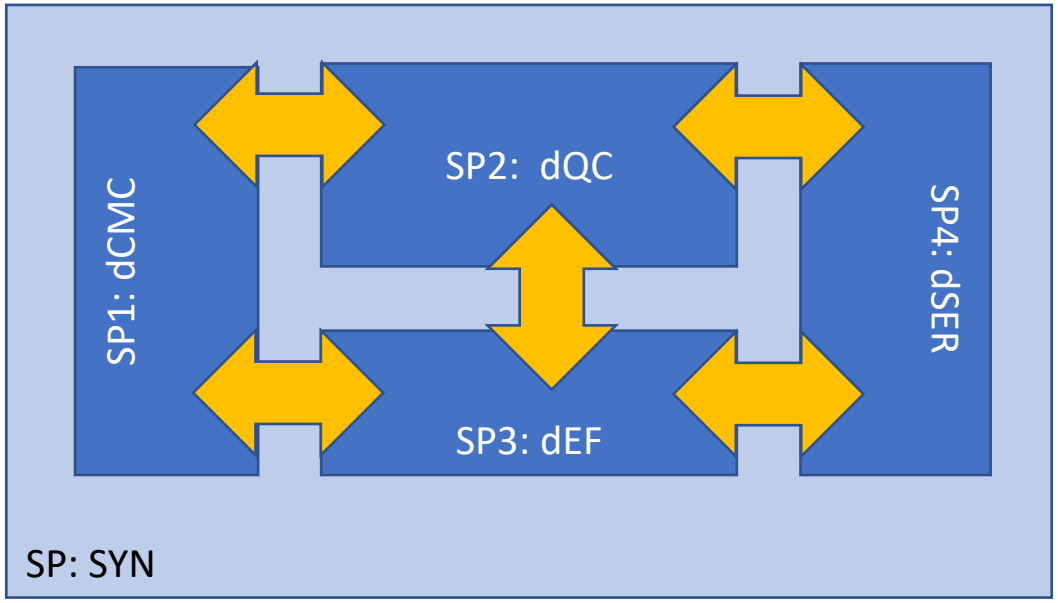
Digitalization definition from the project perspective:

The process of employing digital technologies, such as automation, data mining, machine learning and computer simulations, in combinations with scientific knowledge and market information to transform specific operations

Project Organization

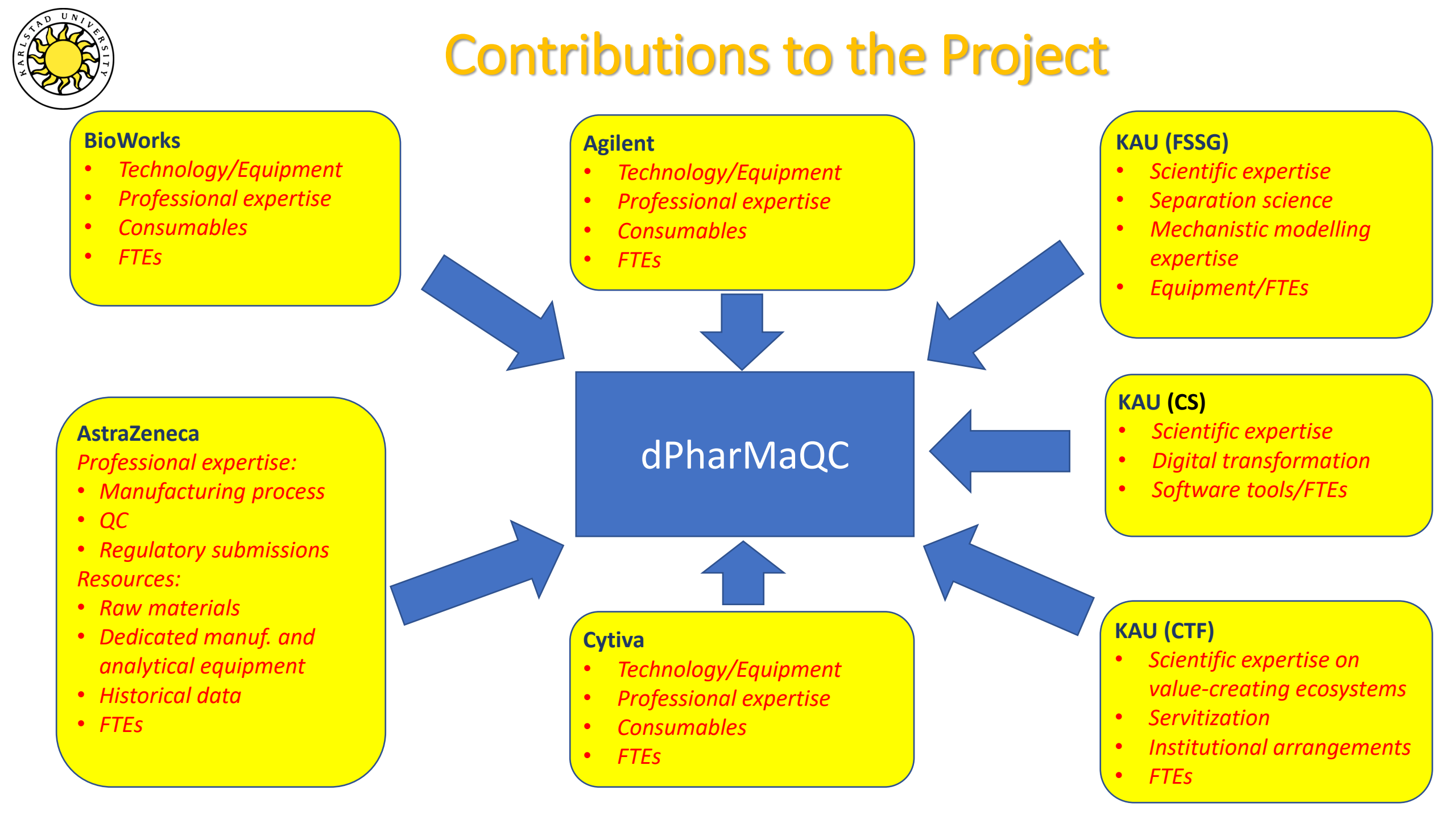
The project consist of five linked sub-projects, each with specific goals and deliverables, that together accomplish the overall project goal,

1) **Overarching Synergy (SYN)**
2) **Digitalized Chemistry, Manufacturing and Control (SP1: dCMC)**
3) **Digitalized Quality Control (SP2: dQC)**
4) **Digital Engine Framework (SP3: dEF)**
5) **Digitalized Servitization (SP4: dSER)**

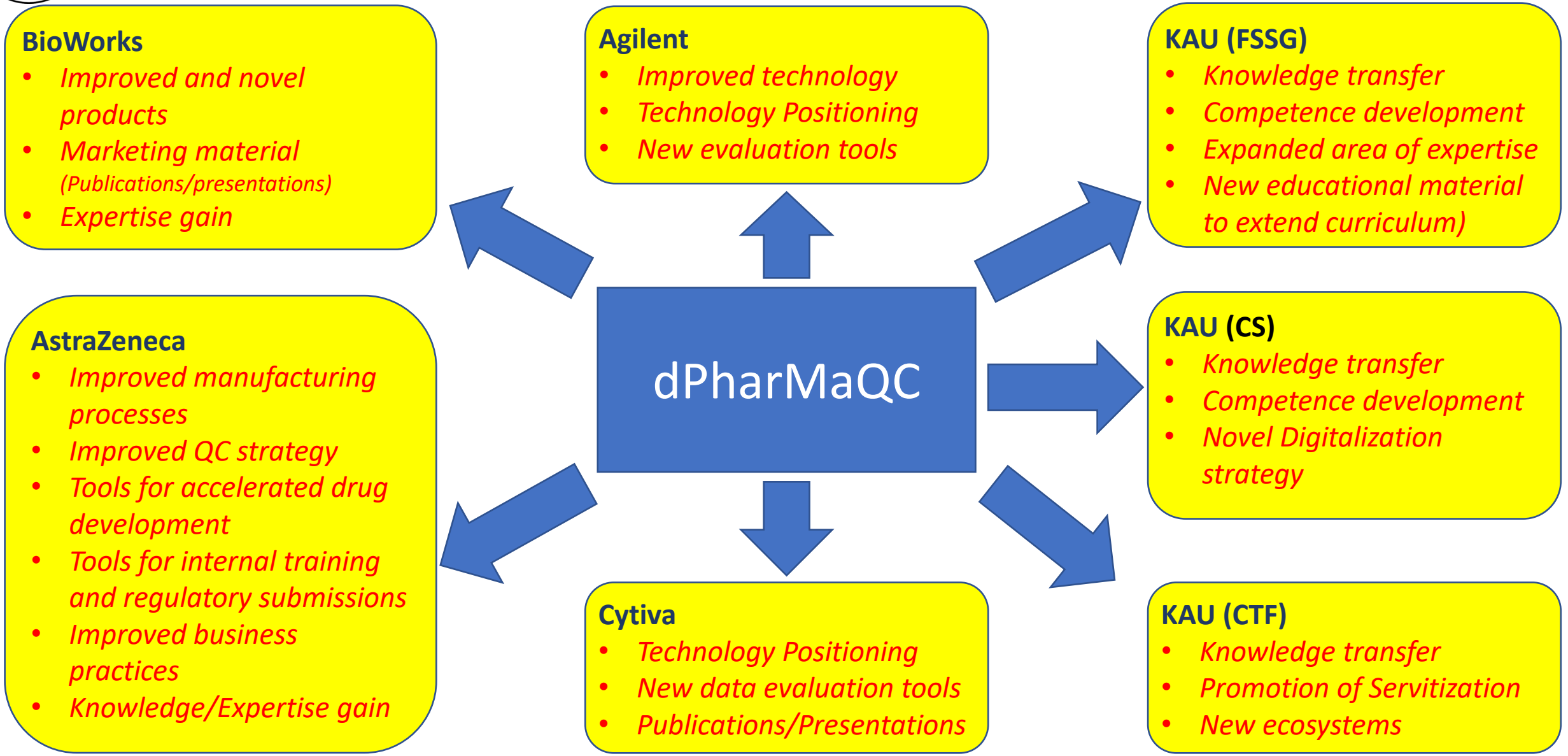


	Partner name	Sub-project				
		SYN	1	2	3	4
Univ.	KAU FFSG	x	x	x	x	
	KAU CS	x			x	x
	KAU CTF	x		x		x
Industry	AstraZeneca AB	x	x	x	x	x
	Cytiva	x		x	x	x
	BioWorks Technologies AB	x	x	x		x
	Agilent Technologies AB	x	x	x	x	x

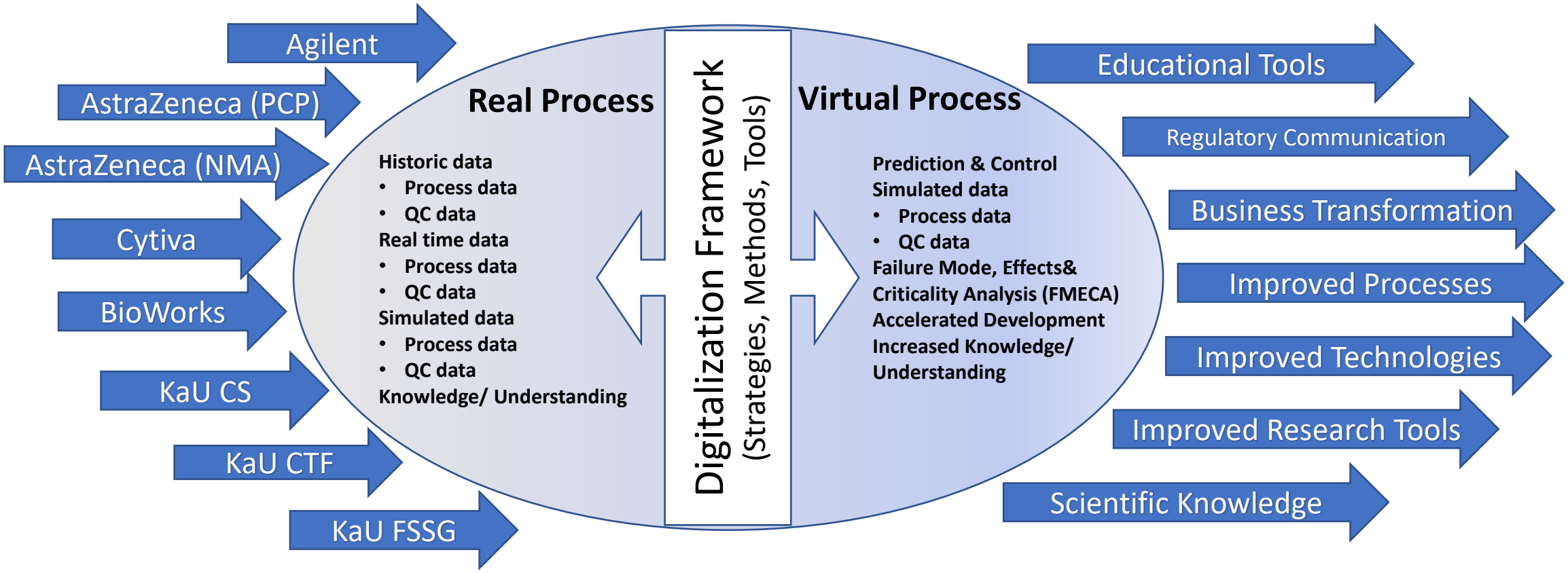
Contributions to the Project



Anticipated Benefits from the Project



The dPharMaQC Project "In a Pill"



Thank You for Your Attention!

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