The tableting process behind the pill

IMAGO – a galenic software

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Who is IMA

Solid Dose Solutions

Founded in 1961, IMA is world leader in the design and manufacture of equipment for the processing and packaging of drugs, cosmetics, tea, coffee and foods. Actual turnover is over 1.5 Billion €.

IMA Active, one of the three Pharma Divisions, is the ideal partner for each solid dose processing phase.

The **IMA Active** solutions are based on individual product lines, but also capable of sharing and cultivating such knowledge within a team.

IMA Active not only provides a vast selection of integrated equipment but also a host of tailored solutions for specific installations.

After years of study and observation **IMA Active** has also taken steps towards **Continuous Manufacturing** with the US company either truly innovative either empowering batch technologies with the IMA Active Research and Development team.

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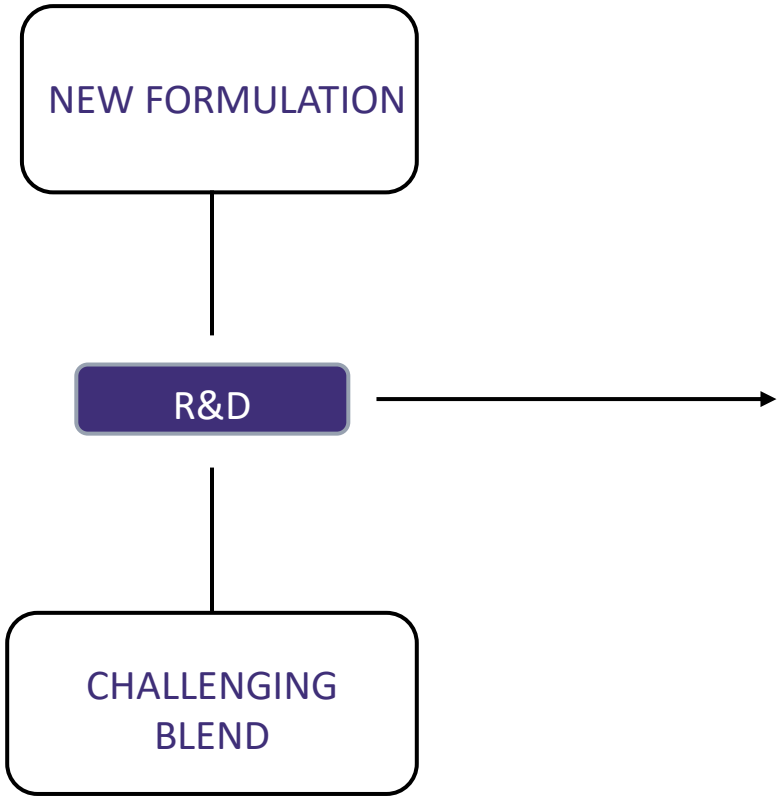
From a scientific point of view



- Detection and analysis of the variables of the compression process.
- Analysis of the powder’s behaviour: stages of development of a formulation, changes within the formulation in order to assess the impact on the process.
- Study of the influence of process parameters on the formulation and tablets.
- Simulation of product behaviour from pilot plants to production machines: scale-up.

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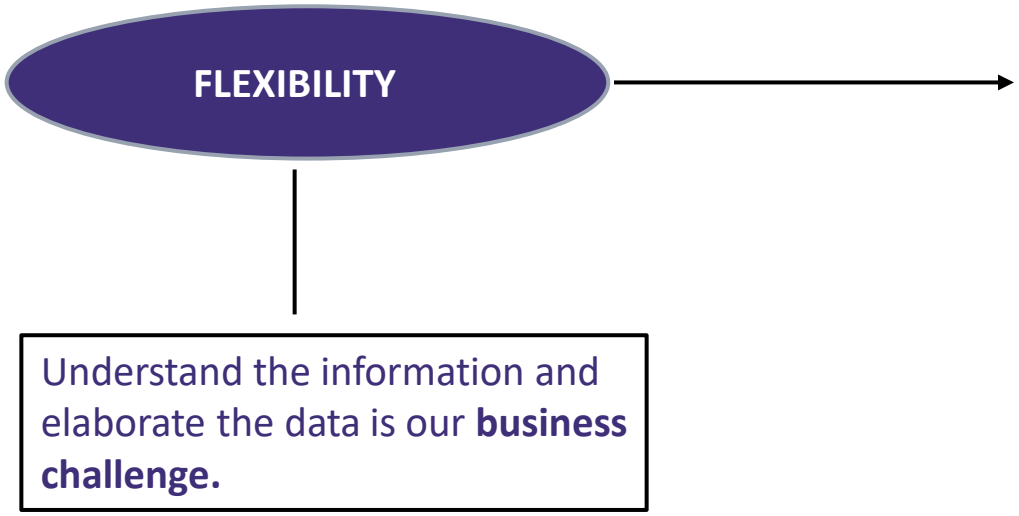
From a scientific point of view



- A system completely integrate whose access is able through a laptop.
- Ready-to-use system with all the analysis instrument (no excel).
- Possibility of customization in case of particular variables to be explored.

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Case study

PLASTIC FORMULATION		
Compounds	**%**	**kg**
Tablettose® 80	66.33	16.583
Vivapur® 102	33.17	8.293
Mg Stearate	0.5	0.125

ELASTIC FORMULATION		
Compounds	**%**	**kg**
Starch® 1500	88.55	22.388
Vivapur® 102	9.95	2.488
Aerosil® 200 Pharma	0.25	0.063
Mg Stearate	0.25	0.063

Comparison between two formulations:

- Curve force vs time.
- Tablets characteristics.
- Tabletability, compactibility and compressibility.

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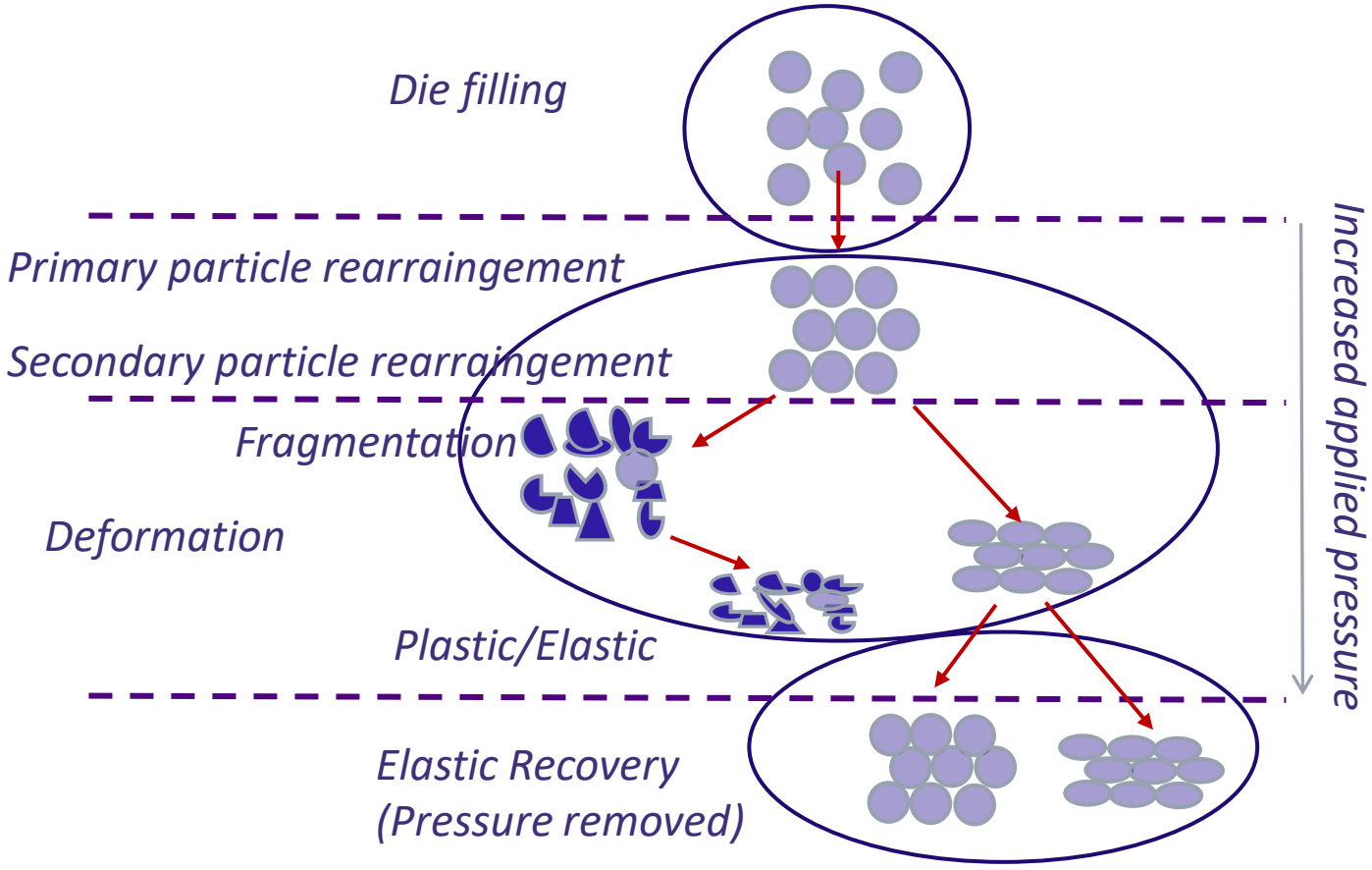
AVEVA

Tableting



How can it be translated in results?

- Typical peak force vs time.
- Tablets features: lower thickness and higher tablet strength.
- Enhanced tabletability, compressibility and compactibility: higher tensile strength as well as solid fraction.

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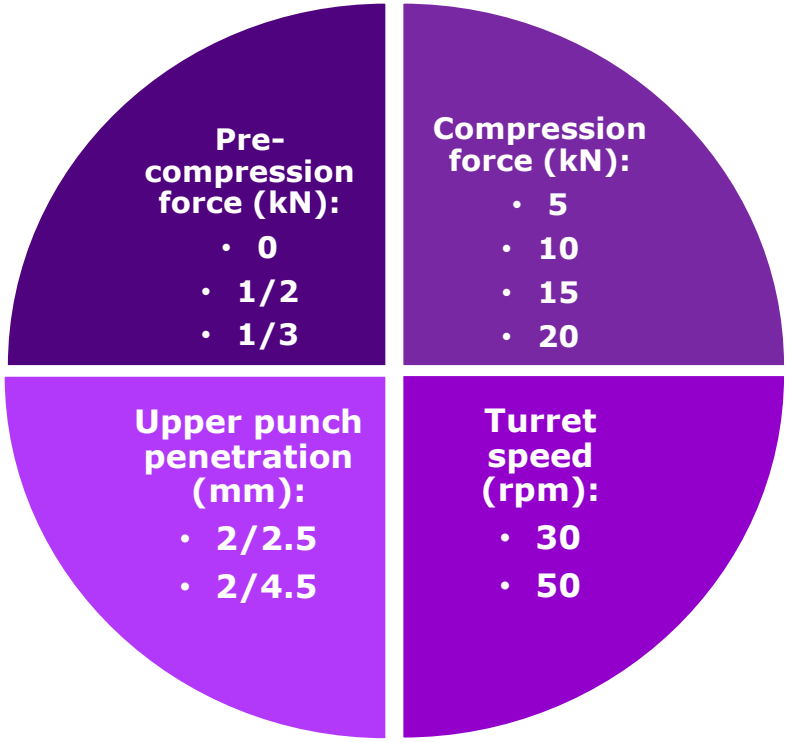
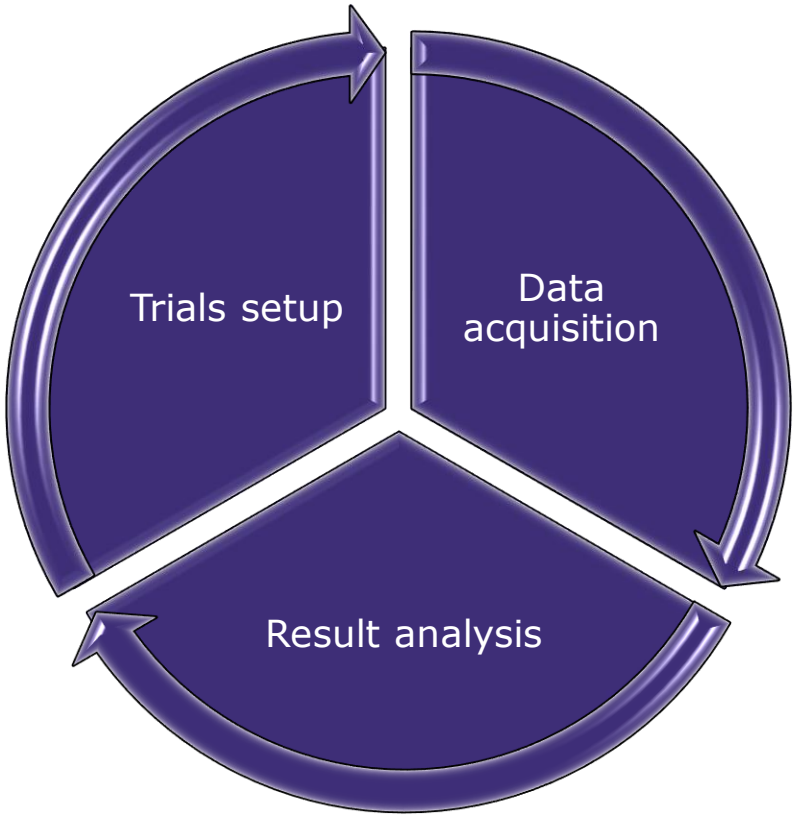
Case study





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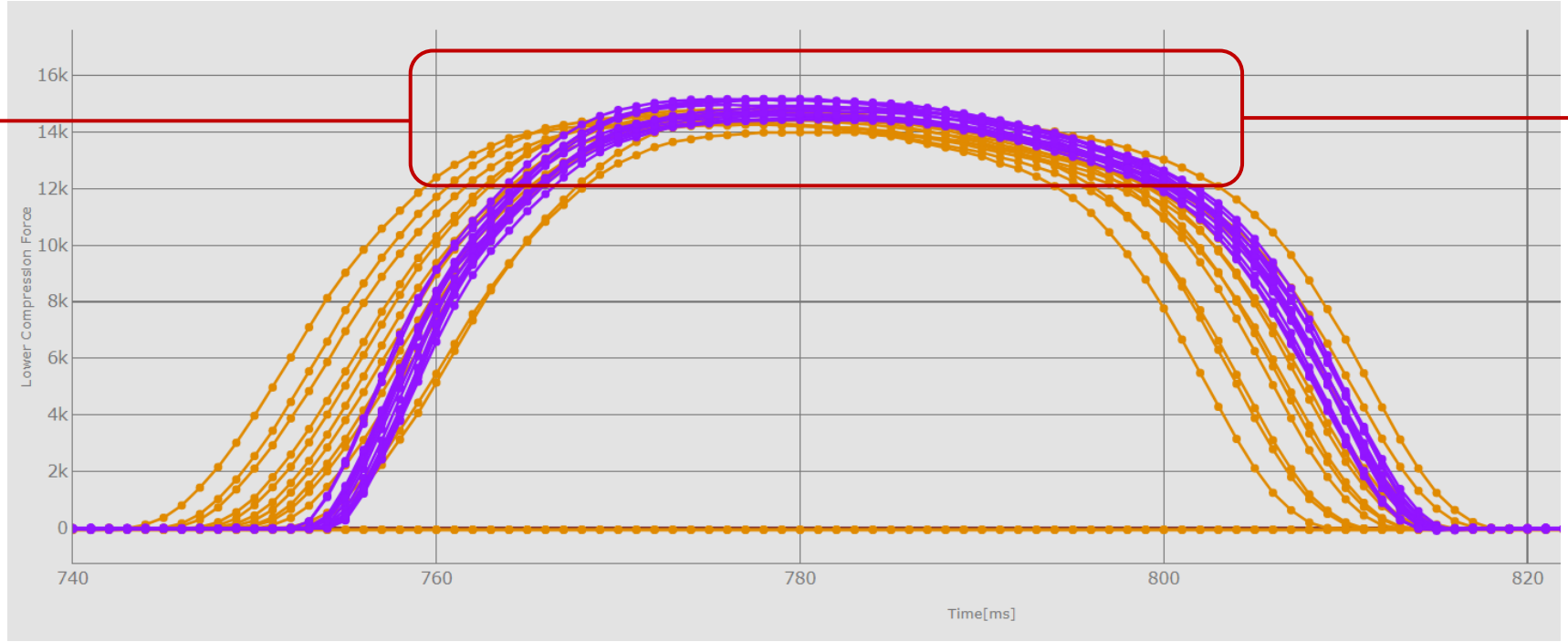
Results: curve forces vs time

Peak shape gives information about powder behavior over tableting phase



ELASTIC:
Visco-elastic proprieties increase the force exterted by the powder bed under tableting generating a more elongated peak.

PLASTIC:
- Tighter bonds
- Less porosity

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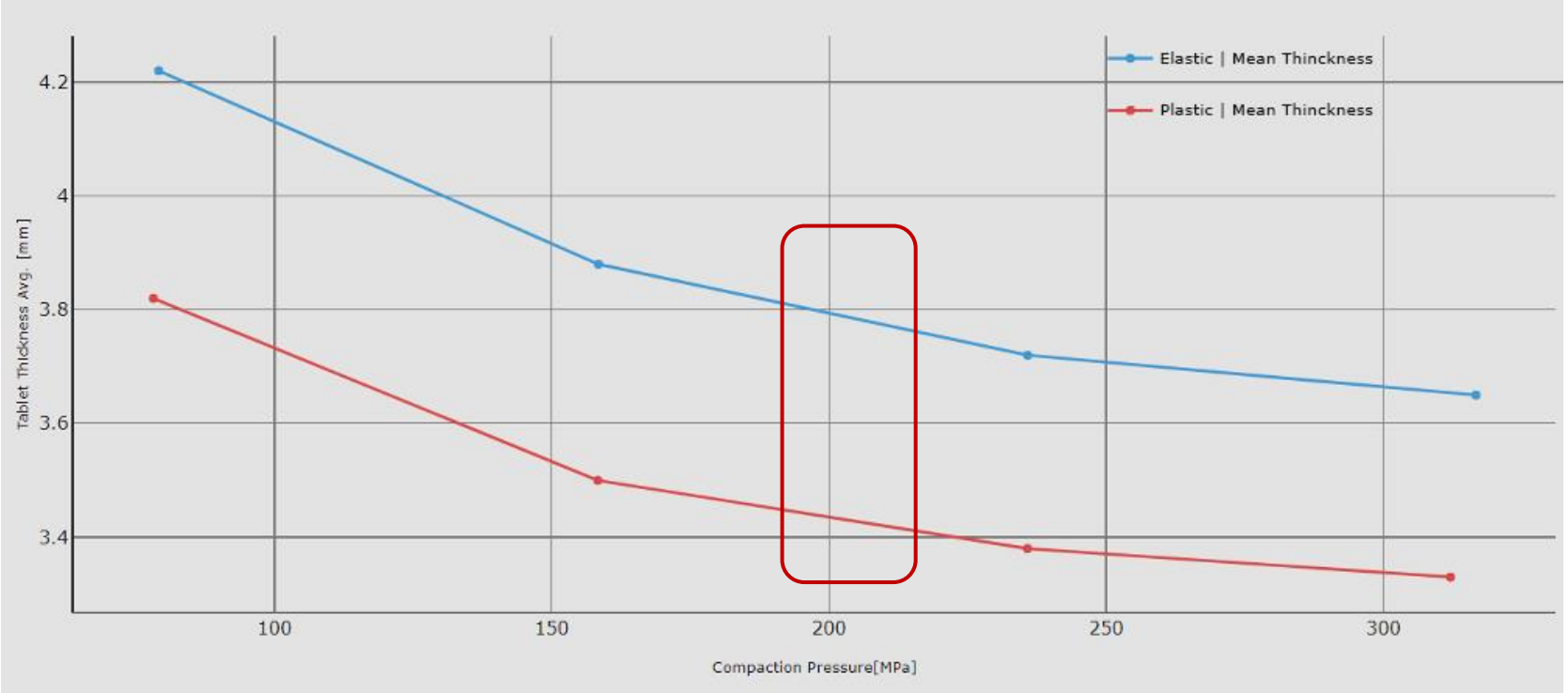
Results: thickness and hardness

At same tablet press parameters and tablets characteristics:

- Thickness is less for plastic formulation due to the tighter bonds that the compression phase is generating.
- Thickenss increases for elastic blends also because of inner tablets relaxation.



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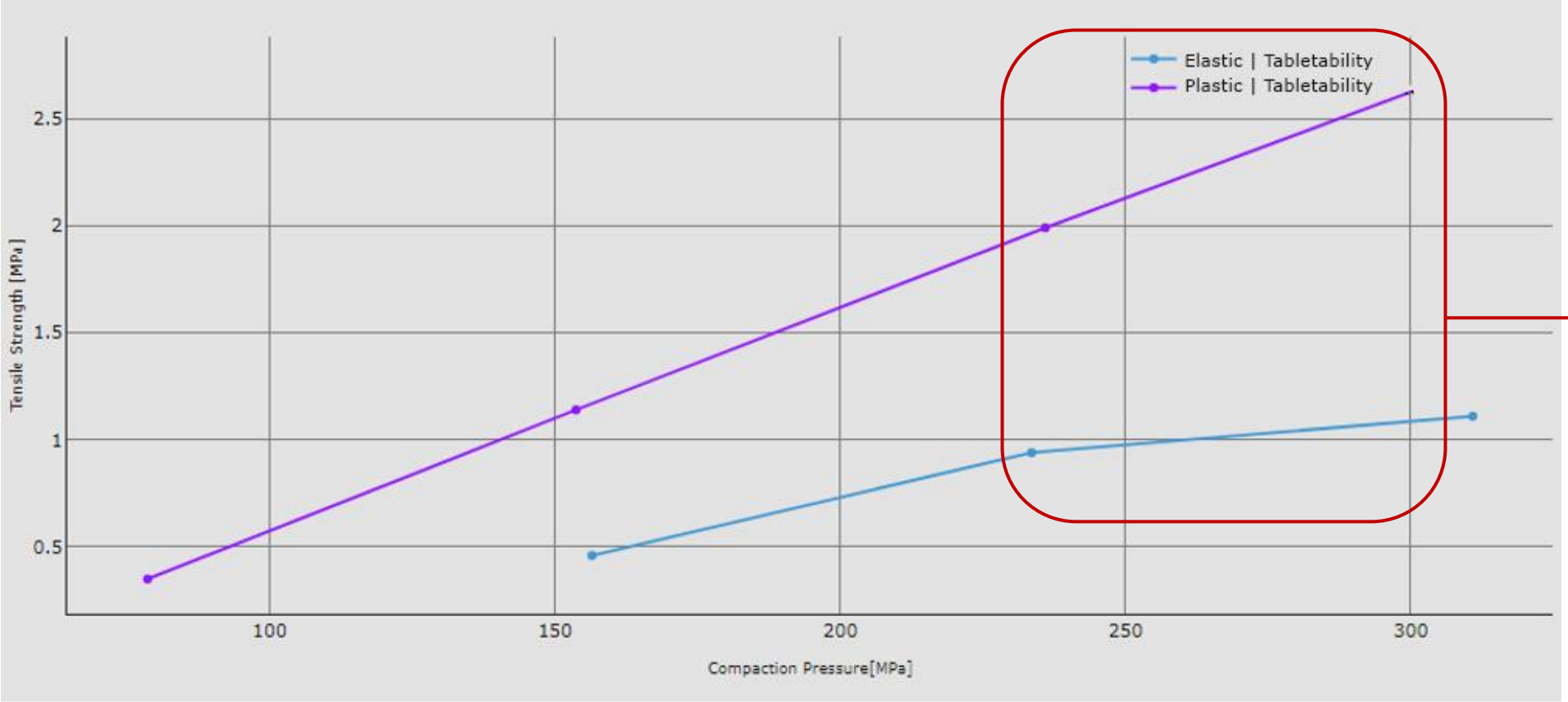
Results: tabletability (hardness)

It represents the powder tendency to be transformed into tablets.



Particles breaking point definitly higher due to increased bond-ability

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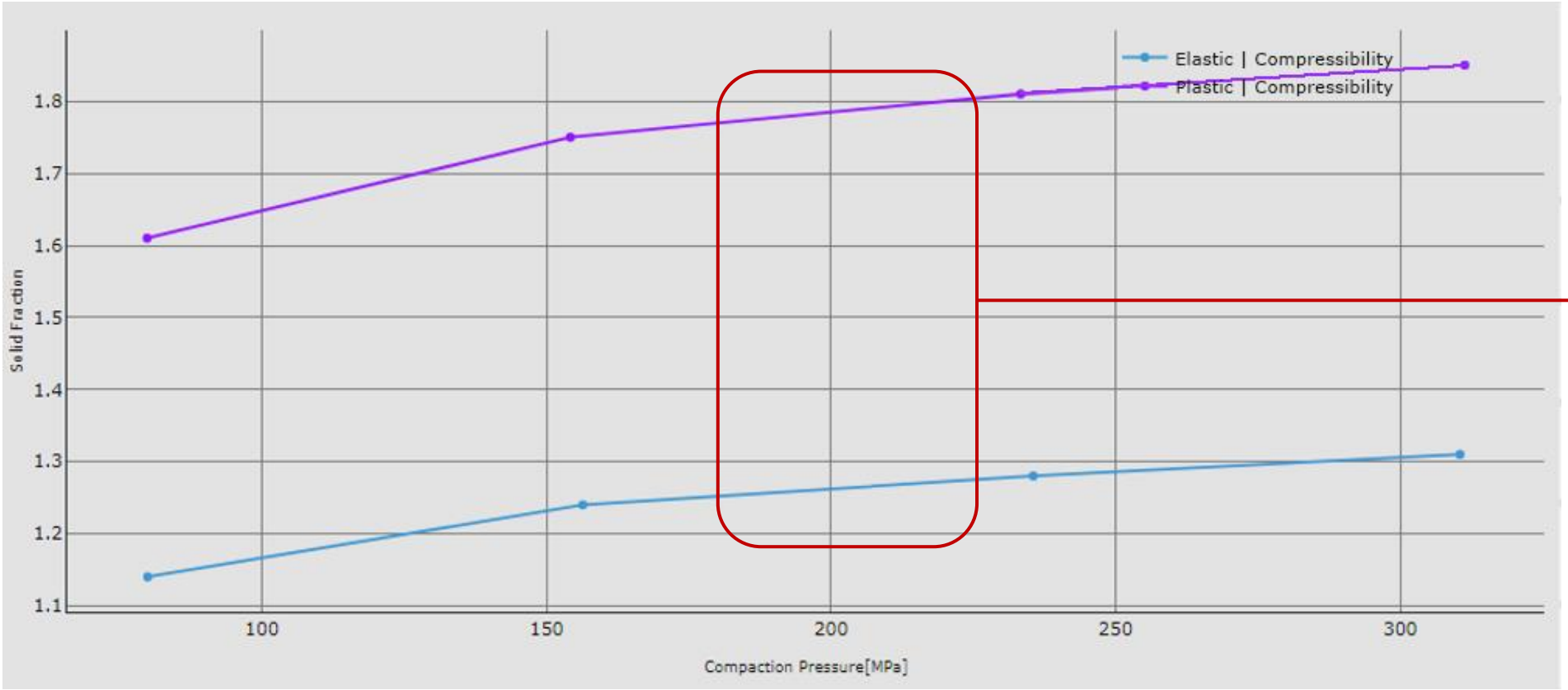
Results: compressibility

It represents the powder tendency to remain compacted under an applied force.



Particles inner tendency to recover their original position

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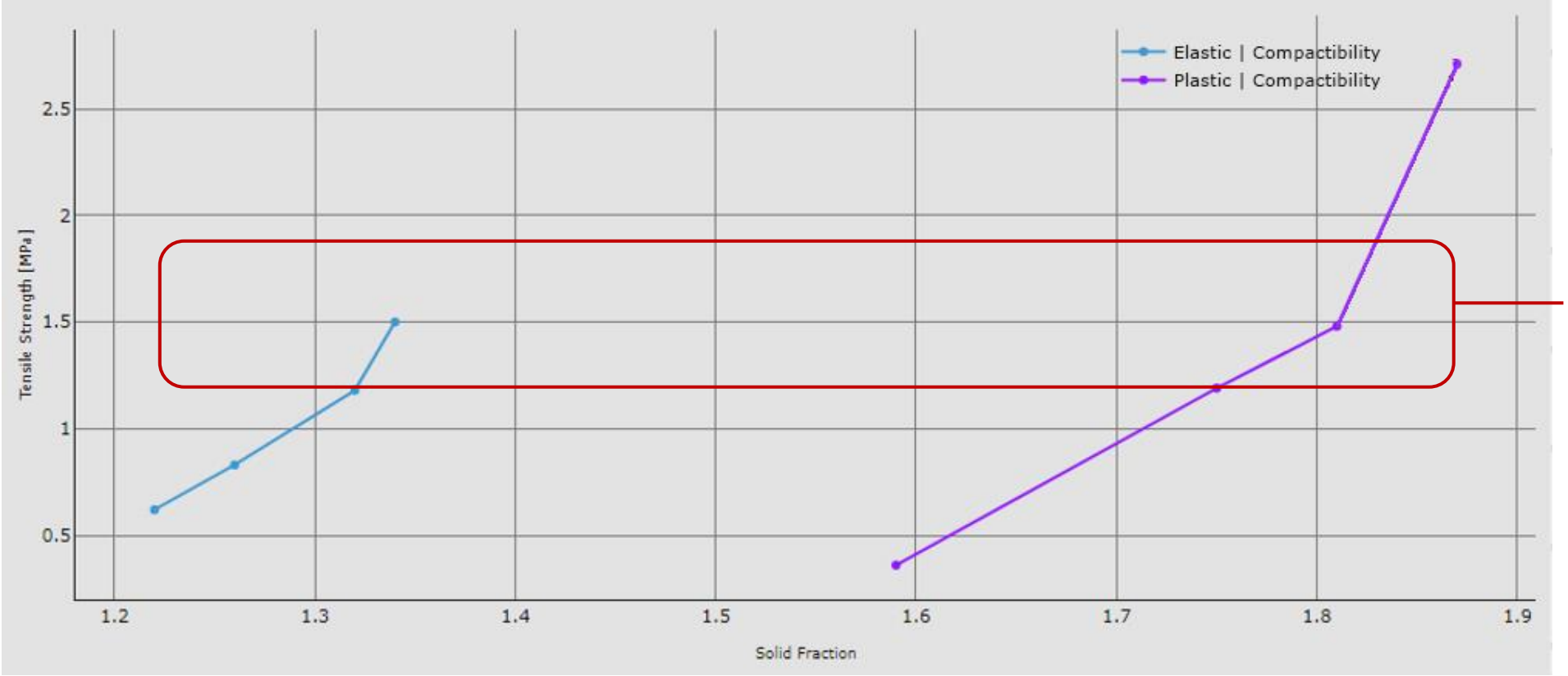
Results: compactability

It represents the powder tendency to reduce its volume if compressed.



- The relaxation *phenomena* affect volume decreasing.
- Tighter bonds improves reduction of volume.

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The challenge

Integrate entire process in one application running on a «real tablet press process» machine.

- Real process data
- Simple to use: data ready to use, organized in the right way
- No overhead to manage data (cleaning, aggregation, …)

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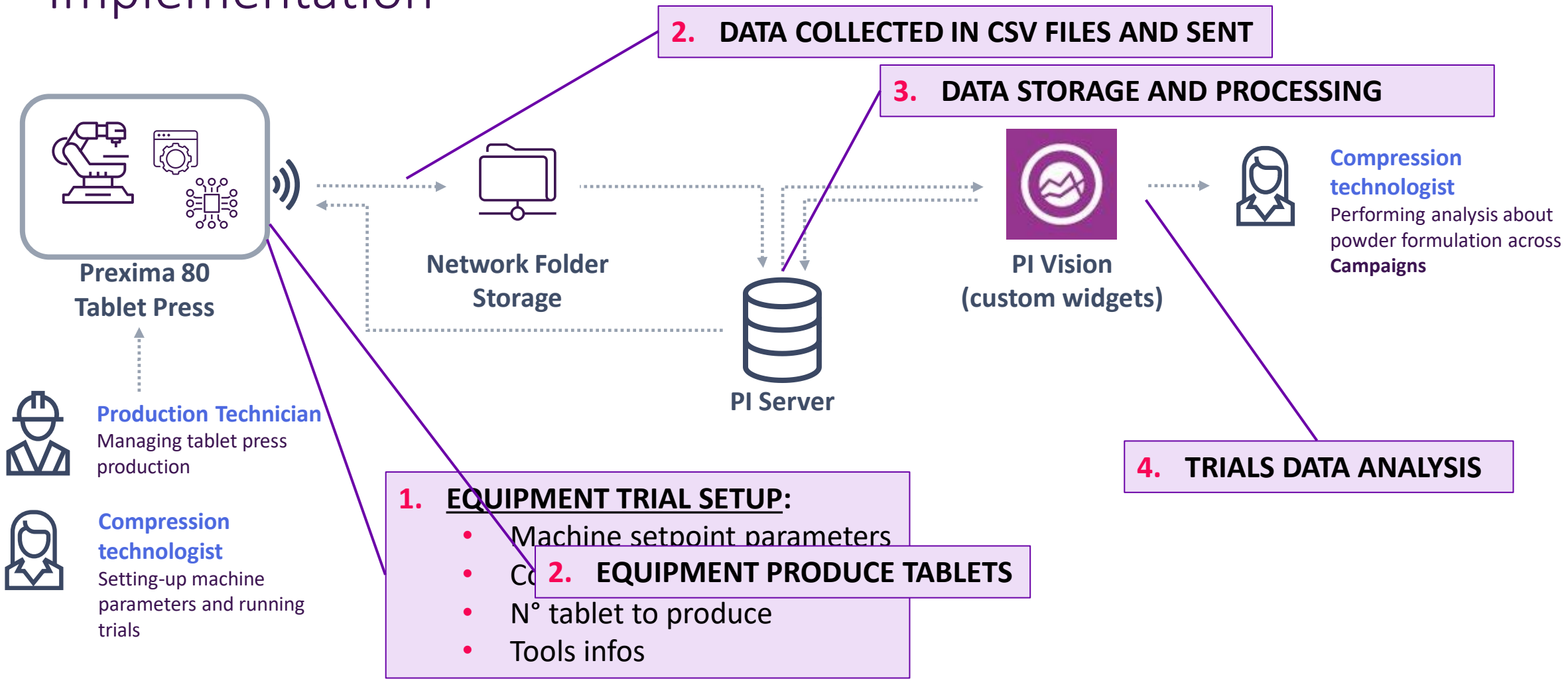
Implementation



Technical solutions – Data collecting

- Collect data from machines:
  - Acquire data from load cells sensors in the tableting process (precompression phase, compression phase, tablet expulsion phase).
    - **Many data every millisecond!!**

- A scalable and reliable solution: **PI UFL Connector (Universal File Loader)**
  - No data lost
  - Acquire a huge amount of data
  - Ease to configure
  - Ease to extend data model

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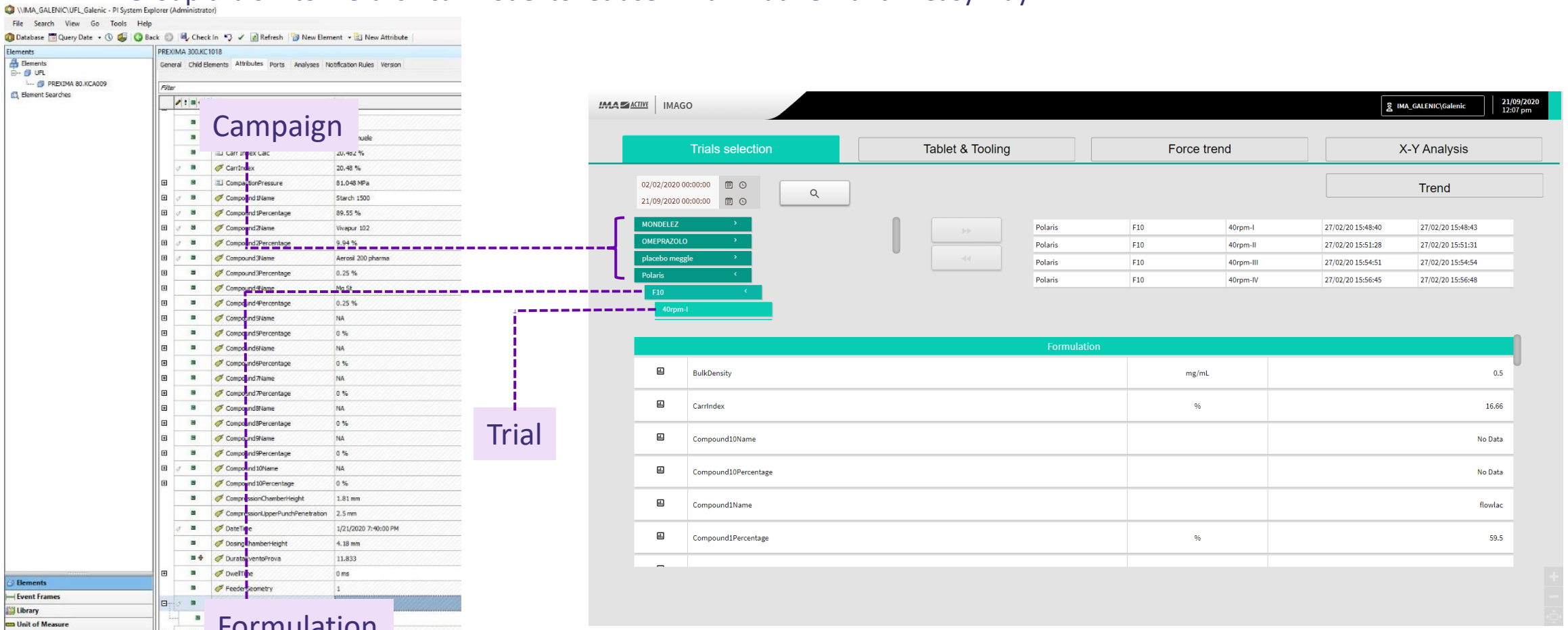
Technical solutions - Modelling

- Quick and easy modelling: **Asset Framework**
  - Group trials into hierarchical model to let user find what he want in easy way.



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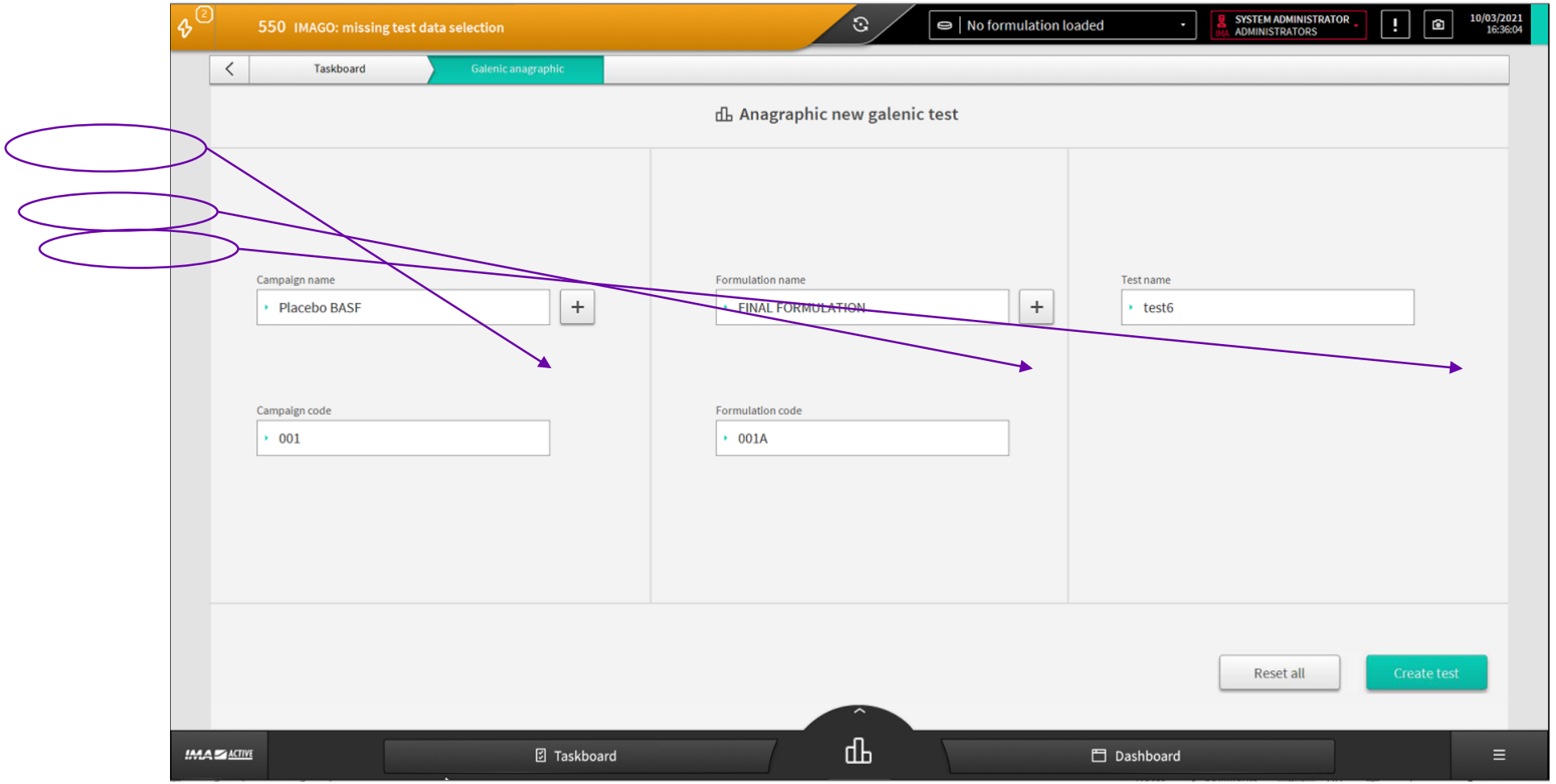
Technical solutions - Interoperability

- Guided process and data flow integration: **PI SQL Client and RTQP Engine.**



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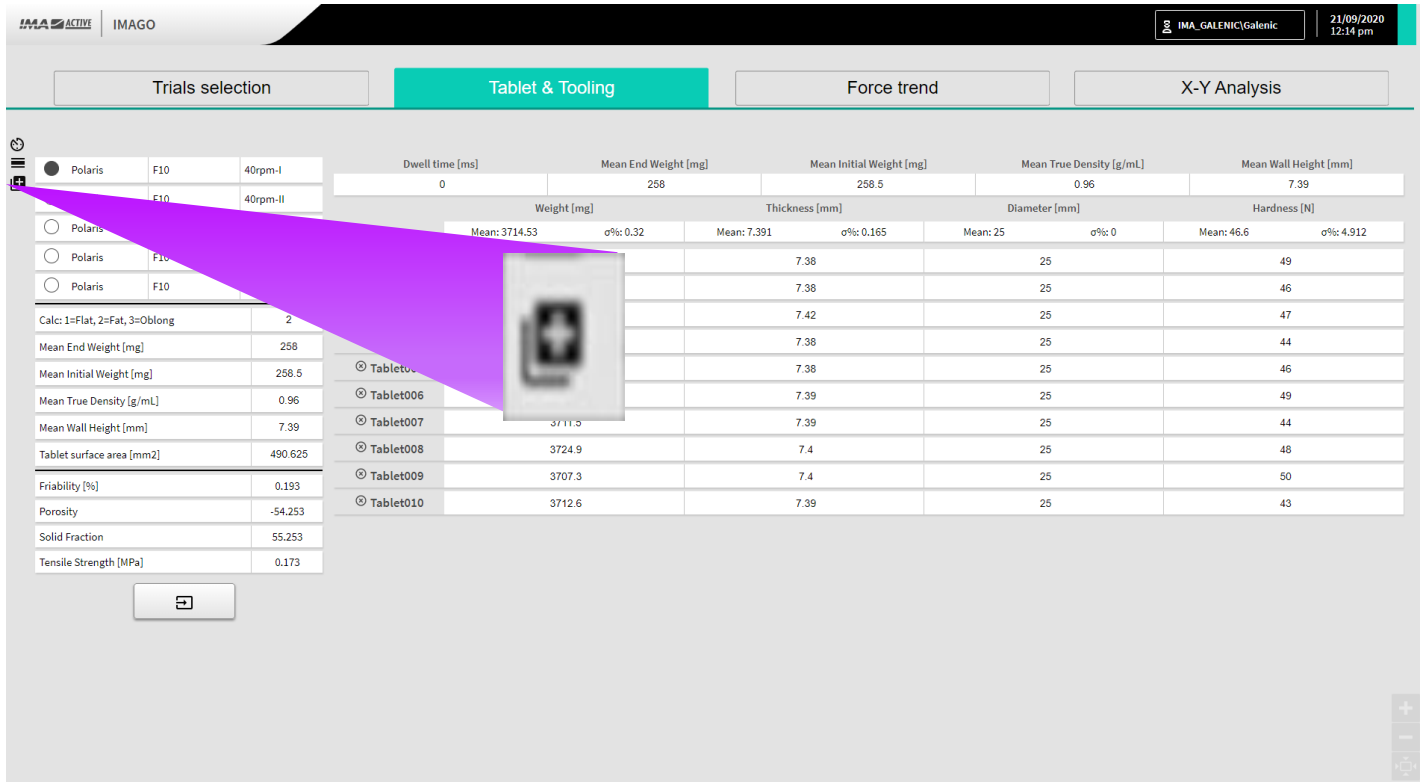
Technical solutions – Enhanced functionality

- Quick and easy modelling: **Asset Framework**
  - Complex analytics from machine raw data.
  - Possibility to input and store missing data during data collecting (*tablets characteristics*).



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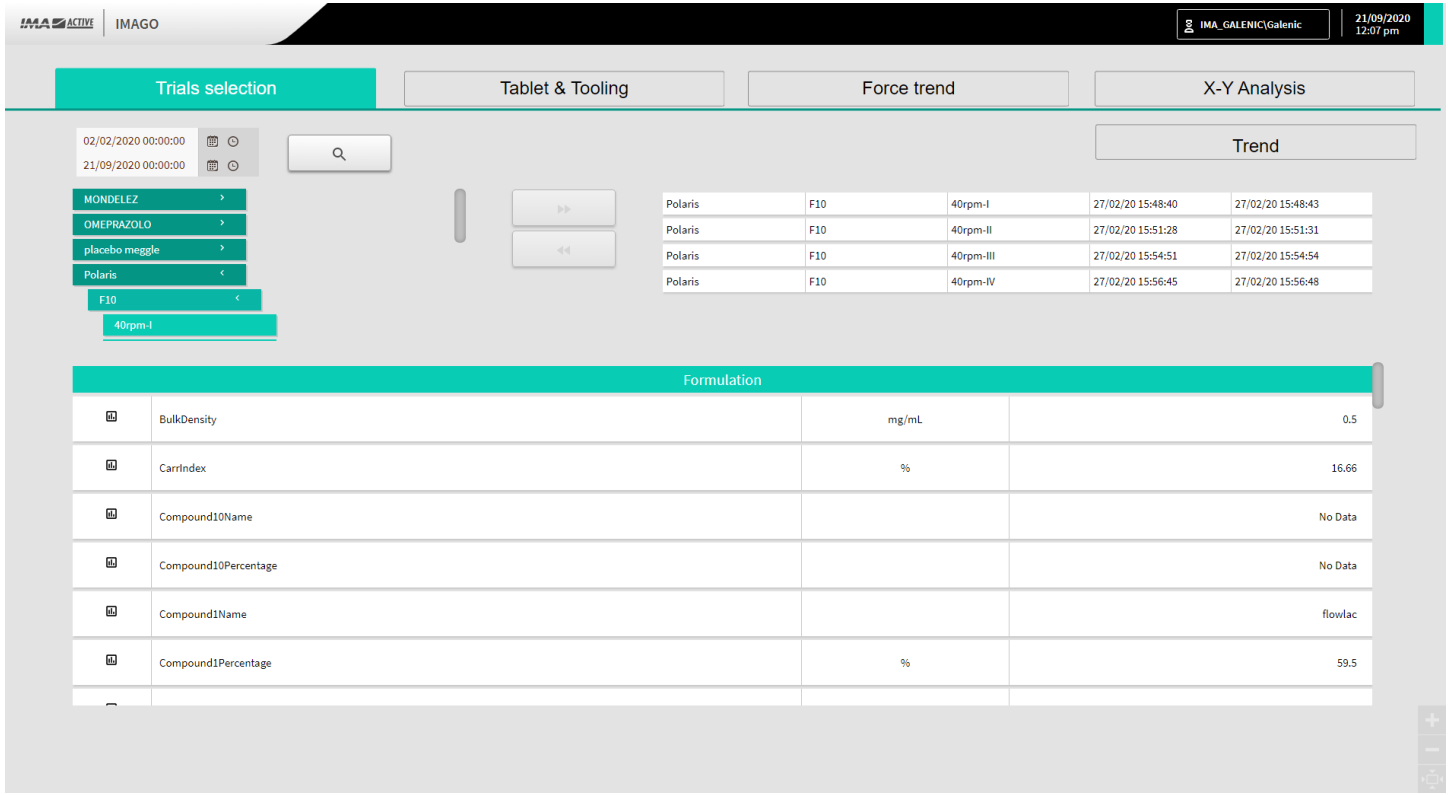
Technical solutions - UX

- Data flow integration: **PI Vision**
  - Front end with same family feeling of machine HMI.



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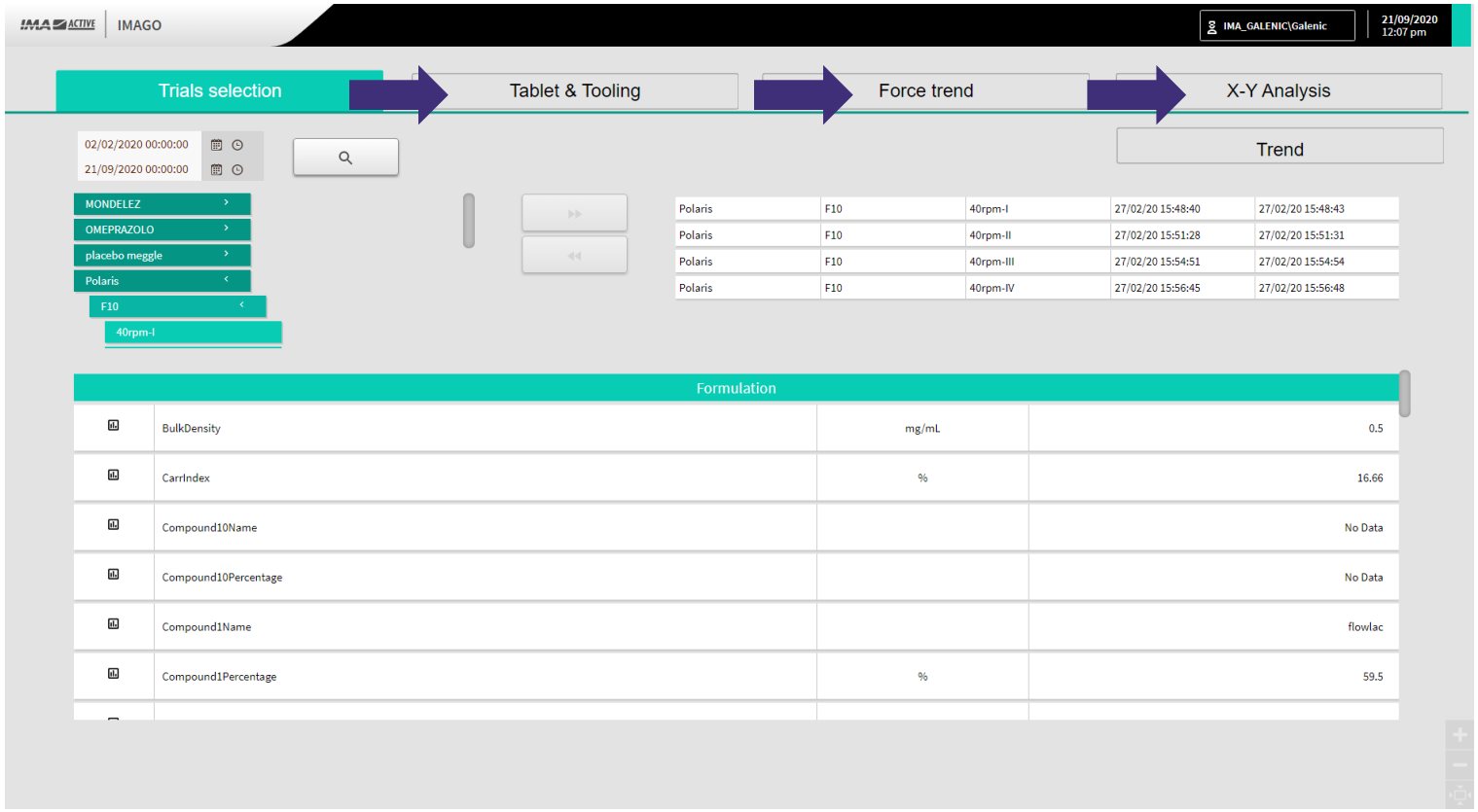
Technical solutions - UX

- All at right place for analysis:
  - Intuitive e guided process
  - Compare data of different trials



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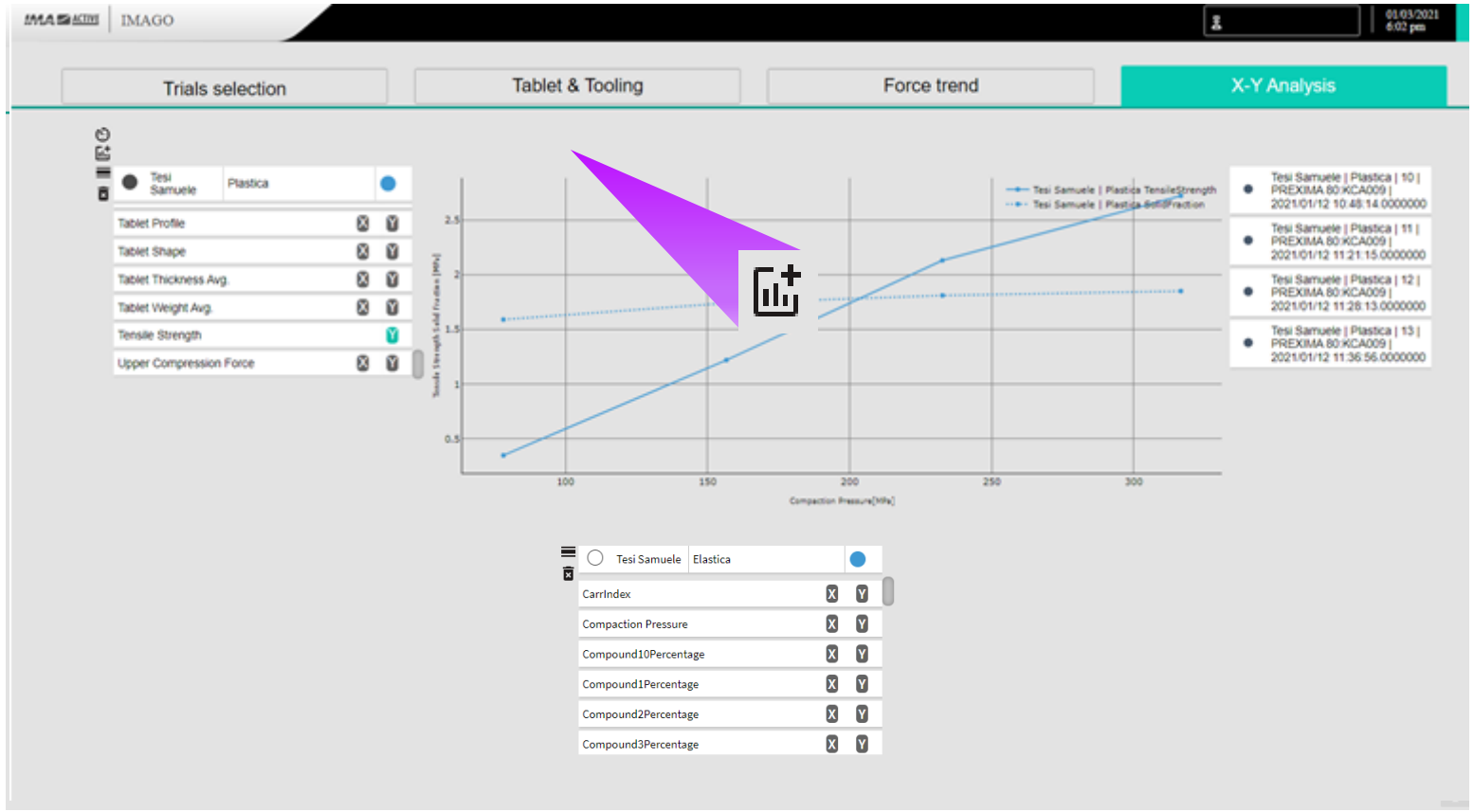
Technical solutions - Analysis

- **Time is not the main driver!** The power of **PI Web API Framework**



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Conclusion

Challenge

Providing to lab user an application to analyze powder formulations:

- Study of compounds characteristics,
- Find correlation among process variables and formulation variables,
- Optimize process of tableting (machinability),
- Scale-up: find optimal process parameters for large production.

Solution

AVEVA PI System (PI Server, PI Vision, PI UFL connector and SQL Client) for:

- Acquire huge amount of data with no data lost,
- Modelling complex concepts and analytics,
- Provide analysis tool with a weak time dependency,
- Guarantee excellent UX.

Benefits

“One suite for all.”

- No need to use different software to acquire, manipulate and analyze data,
- All data accessible and stored in the right place,
- Easy to adapt to different analysis scenario,
- Interact with different tools and upper systems.

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Questions?

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Please remember to…

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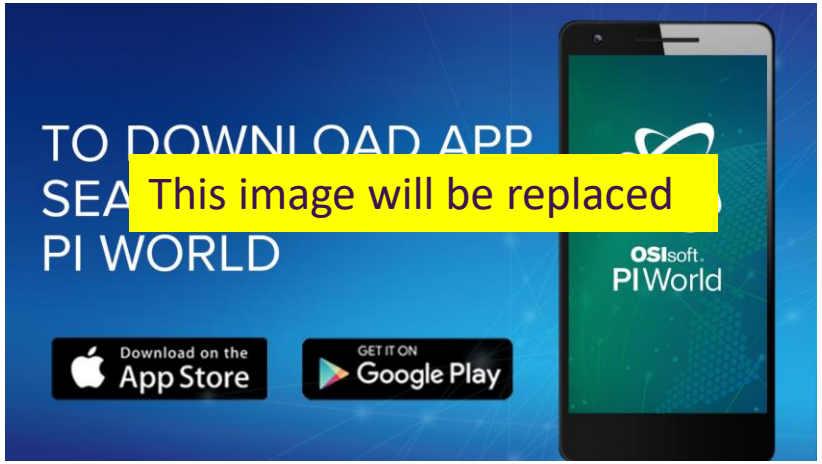
- Navigate to this session in the mobile agenda for the survey



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