

Who we are?

- Mosaiques Diagnostics GmbH, an SME located in Hannover (Germany), is a worldwide leader in clinical proteomics with emphasis on diagnostics, spanning from pre-clinical developments until phase IV clinical trials.

Why do we need to perform a clinical trial?

- We have developed a drug repurposing pipeline by analyzing multi-omics integrated signatures and identified exemestane as a novel drug solution for patients with terminal stage bladder cancer. We have validated the effect of exemestane in preclinical studies demonstrating its anticancer role.
- Execution of a multinational clinical study phase I/II is needed to confirm the therapeutic efficacy of exemestane in patients with bladder cancer with no available treatment option anymore.

What are the EMA related challenges we face?

- Missing information in EMA's guidelines with regard to the requirements for repurposed drugs (sufficiency of preclinical data, challenges of clinical studies involving repurposed drugs, authorization issues).
- Approaching in addition National Authorities appears mandatory, which is associated with high fees and communication with several regulators from different countries, making the trial execution even more complicated.

Suggested solutions:

- 1. Update guidelines to include the requirements for repurposed drugs.**
- 2. Coordinate scientific advice between EMA and National Authorities to unify/harmonize procedures.**
- 3. Opportunity to fund (or waive) fees for SME's who provide solid preclinical evidence on the potential of the drug candidate to be tested.**