

MICROB-PREDICT

Alb-Trial – the clinical trial of Microb-Predict

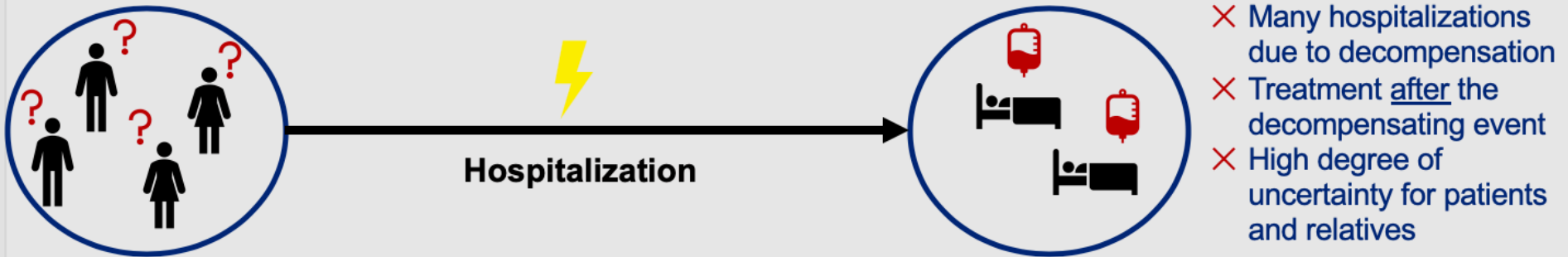
Professor Aleksander Krag
Head of the Clinical Trial (WP7)

Online ELPA Patient Event, 8th of July 2020

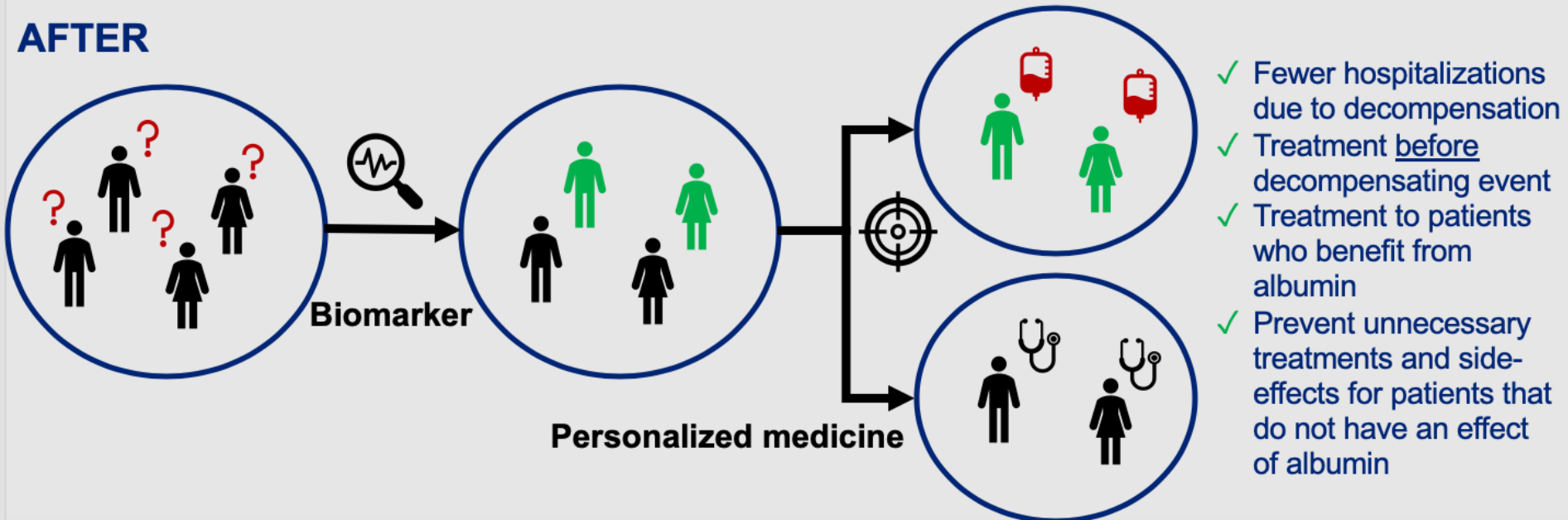


This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 825694.

BEFORE

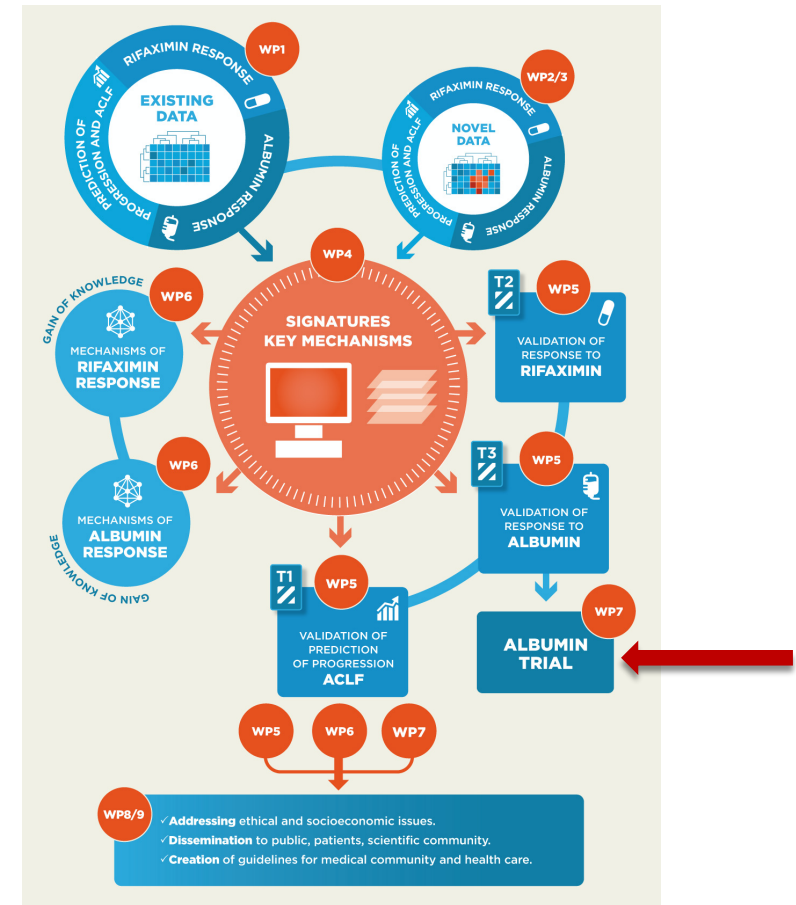


AFTER



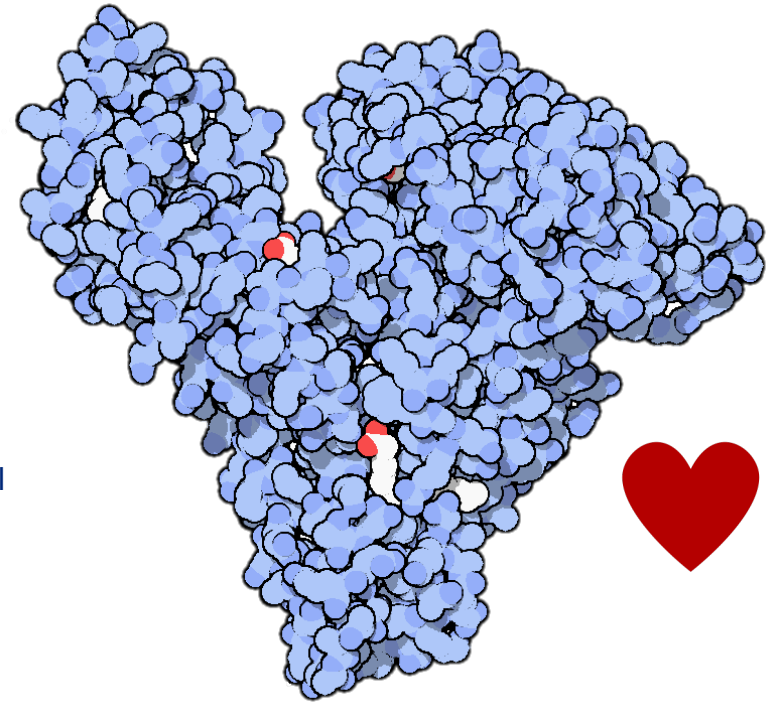
The goal & role of Alb-Trial

- **Alb-Trial** will be a **state-of-the-art clinical trial** aiming at **validating the microbiome-based biomarker** developed within the framework of **Microb-Predict**.
- The **short time** from **biomarker development** to **validation** in a **clinical setting**, will be **unprecedented** in the field of **liver diseases**.
- This will allow us to **implement personalized treatment guidelines** quickly to the **benefit** of **patients, relatives** and the **community** as a whole.



About human albumin

- **Albumin** is the most **abundant protein** in the human plasma, and is normally **produced** by the **liver**
- Albumin as a medical product has been used **since the 1940s**
- It is already **recommended** to **liver patients** in the following scenarios:
 - Large volume **removal of fluid** from the **abdominal cavity** (“large-volume paracentesis”)
 - **Infection** in the **abdominal cavity** (“spontaneous bacterial peritonitis”)
 - **Renal failure** in relation to liver disease (“hepatorenal syndrome”)
- **Healthy voluntary plasma donors** are normally the **source of the albumin** that are used to treat patients
- **Human albumin** is known to be a **safe and tolerable product** by the majority of patients



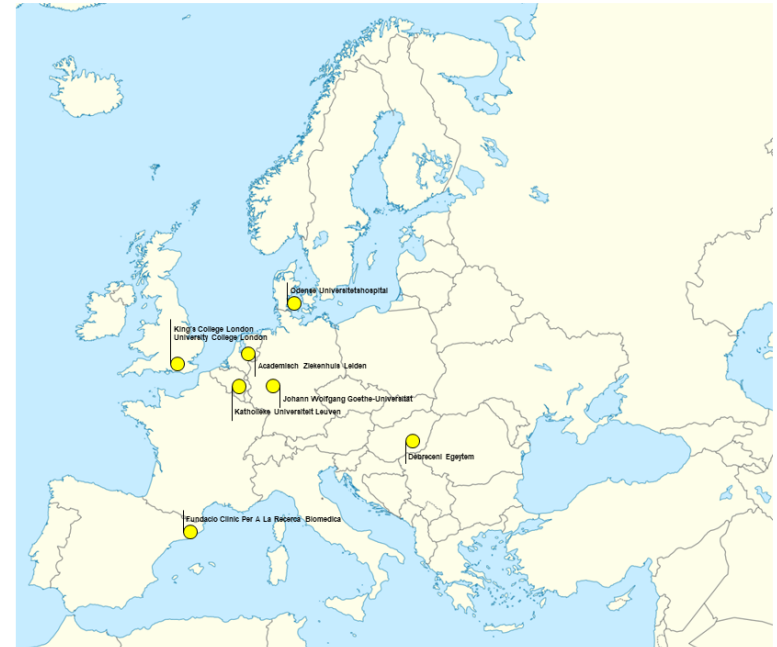
Chemical structure of human albumin. Looking closely it has the shape of a **heart**.

Source: *PDB-101, Molecule of the Month, January 2003*



About Alb-Trial (clinical study)

- Alb-Trial will **include 240 patients** from **8 hospitals** in **7 countries** in **Europe**
- The study will *commence* in **June 2022** and be *completed* in **September 2024**
- Patients are potentially **eligible** to **participate** regardless of the **cause of liver disease**
- **All participants** will in addition to their study treatment receive their **standard medical treatment** and **human albumin infusions** as recommended by **European guidelines** (previous slide)



Study site countries

- | | |
|-------------------|-----------|
| ➤ United Kingdom | ➤ Germany |
| ➤ The Netherlands | ➤ Hungary |
| ➤ Belgium | ➤ Denmark |
| ➤ Spain | |



About Alb-Trial (clinical study)

- The study will be a **double-blinded placebo-controlled** trial to ensure results of the **highest scientific quality**.
- The study period for each participant will be **6 months**
- During the study period participants will have **intravenous infusions of human albumin or saline** performed by research nurses who also check for **participants well-being**.
- Infusions will happen every **10th day** (± 3 days) in **covered black bags and lines** to ensure that **no one can see the content** of the bags and lines.



Thank you for listening!
Questions? 😊



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