MICROB-PREDICT

Alb-Trial – the clinical trial of Microb-Predict

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

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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.

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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
- The Netherlands
- Belgium
- Spain
- Germany
- Hungary
- Denmark
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? 😊