PRESENTATION OF THE INDUSTRIAL IMPLEMENTATION ACTION PLAN OF THE "ITALIAN MICROBIOME INITIATIVE FOR IMPROVED HUMAN HEALTH AND AGRO-FOOD PRODUCTION"

NOVEMBER 26, 2020

www.siitgroup.com

The view of the industry

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A member of:
federSalus

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SIIT highlights

SIIT is an Italian private innovative healthcare company involved in development and manufacturing of more than 1200 products in 60 different markets for more than 190 Pharmaceutical & Nutraceutical companies all over the world.

- Contract Development & manufacturing in GMP, ISO 13485 and ISO 22000 health food supplement, Medical Devices and OTC in solid & liquid forms.
- 4 plants, 3 logistic hubs, 500 employees 100 manufacturing & packaging lines in dedicated controlled production areas

- Internal R&D teams dedicated to;
- develop consumer added value products to license out , principally in Gastrointestinal, Cough & Cold and Woman's health care.
- develop technologies to improve absorption, biological activity and stability of finished products

Several of the priorities identified in the Italian Microbiome initiative vision document are of primary interest for the Italian pharma and agri-food public private partnerships belonging or mobilized by the ALISEI and CLAN national Technology Clusters. SIIT shall represent industrial actions priority in nutraceutical (food supplement) field

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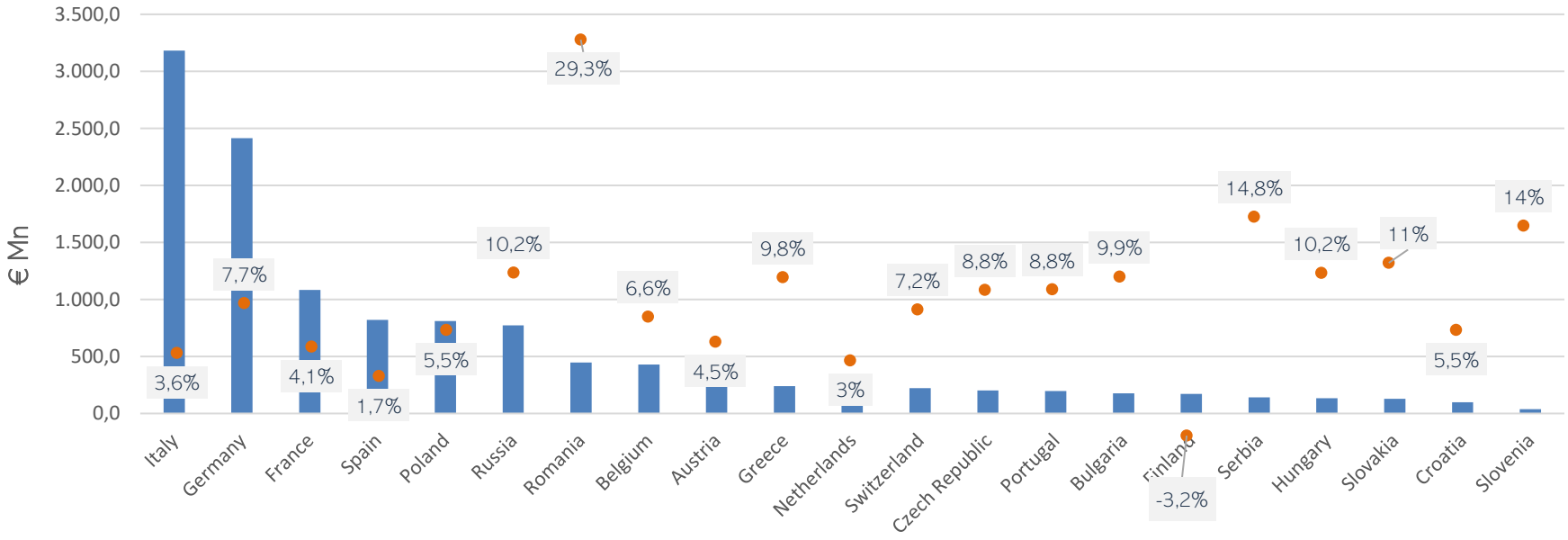
Over half of total Food Supplements sales in Europe are driven by Italy, Germany and France

Italy is the **main market** with sales of € 3.6 billion, accounting for **27%** of the total market, this explain the highest Italian competences in terms of marketing, distribution & production.

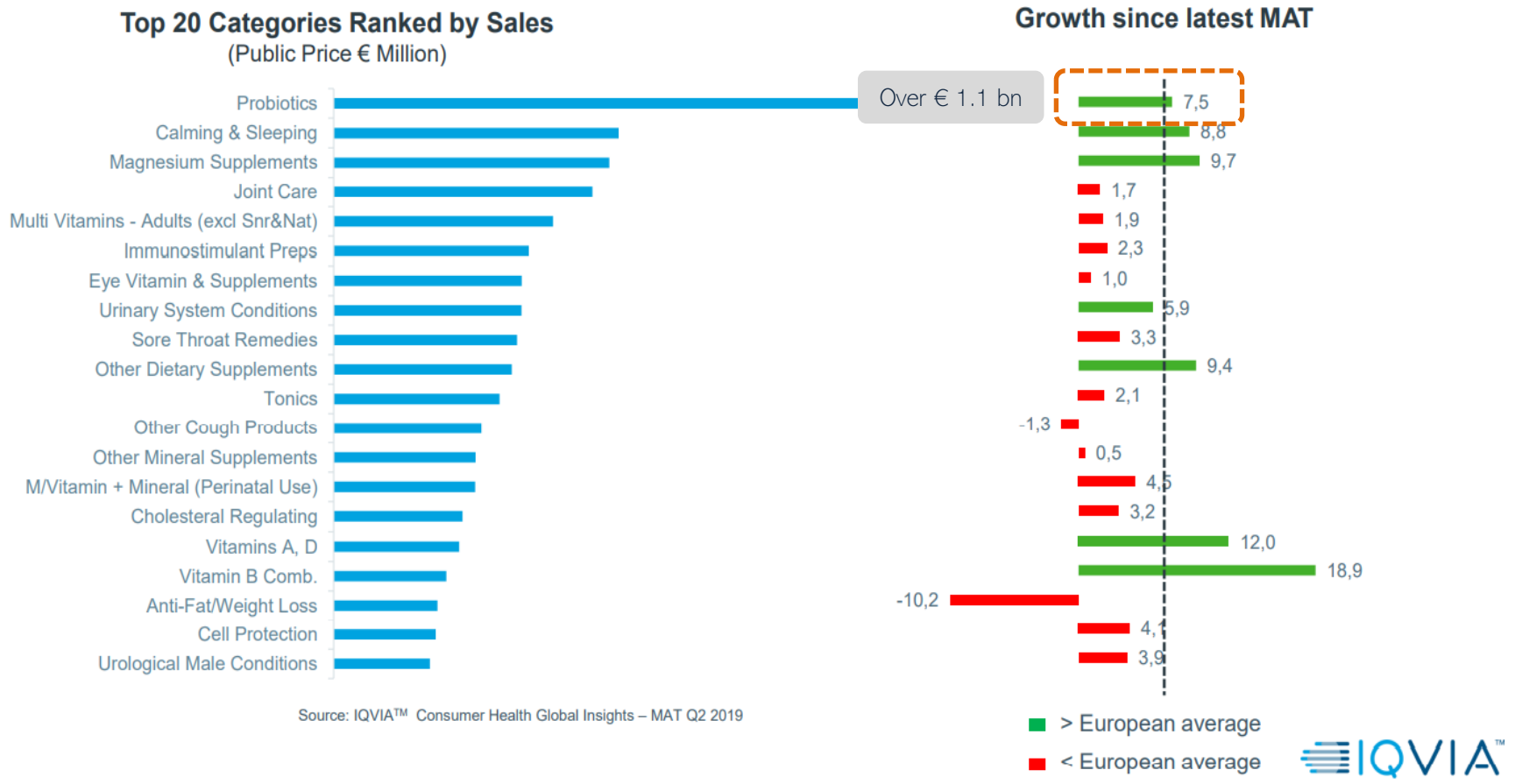
Europe
Total value: € 13.2 bn
Value growth: +6.4%

European Food Supplements Value Sales – MAT Q4 2019
(Euros, Public Price)



Source: IQVIA™ Consumer Health Global Insights

Probiotics are the Largest Category in the European Food Supplements Market (2019)



Source: IQVIA™ Consumer Health Global Insights – MAT Q2 2019

Source: IQVIA, data processing
Classification for market analysis purposes: health claims are subject to Regulation (EC)1924/06

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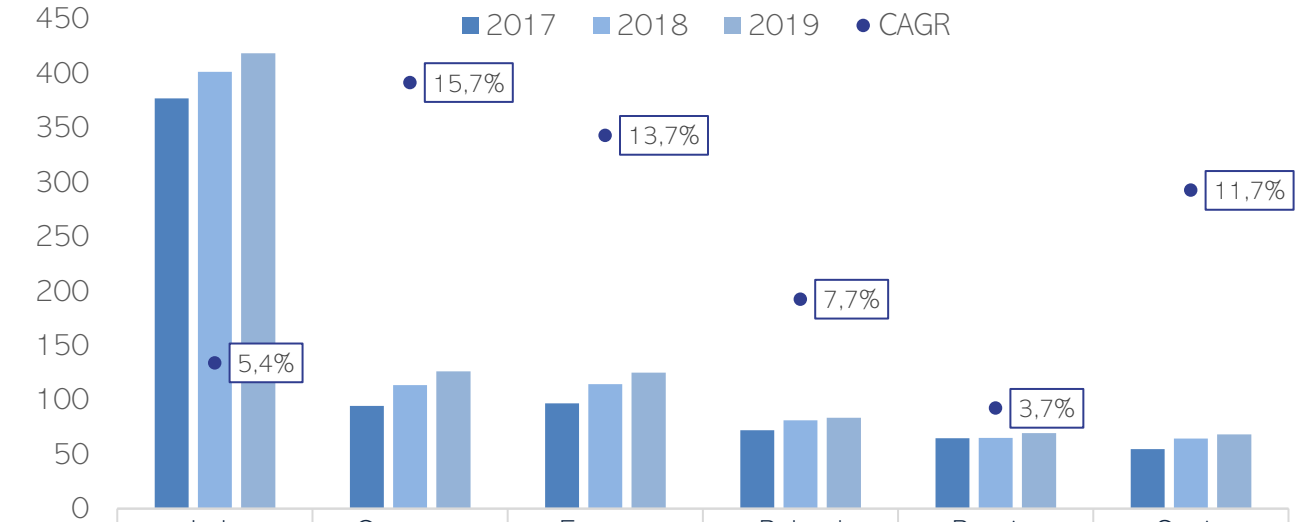
Italy is the largest Probiotic Supplements Market in Europe with 38% share value

Over the past three years, Germany, France, Spain and Poland have grown with sales rising by 15.7%, 13.7%, 11.7% and 7.7% (2017 – 2019 CAGR)



	Italy	Germany	France	Poland	Russia	Spain
2017	377	94	97	72	65	55
2018	401	113	114	81	65	64
2019	418	126	125	84	70	68
CAGR	5,4%	15,7%	13,7%	7,7%	3,7%	11,7%

Source: IQVIA, MAT December 2017 - 2019

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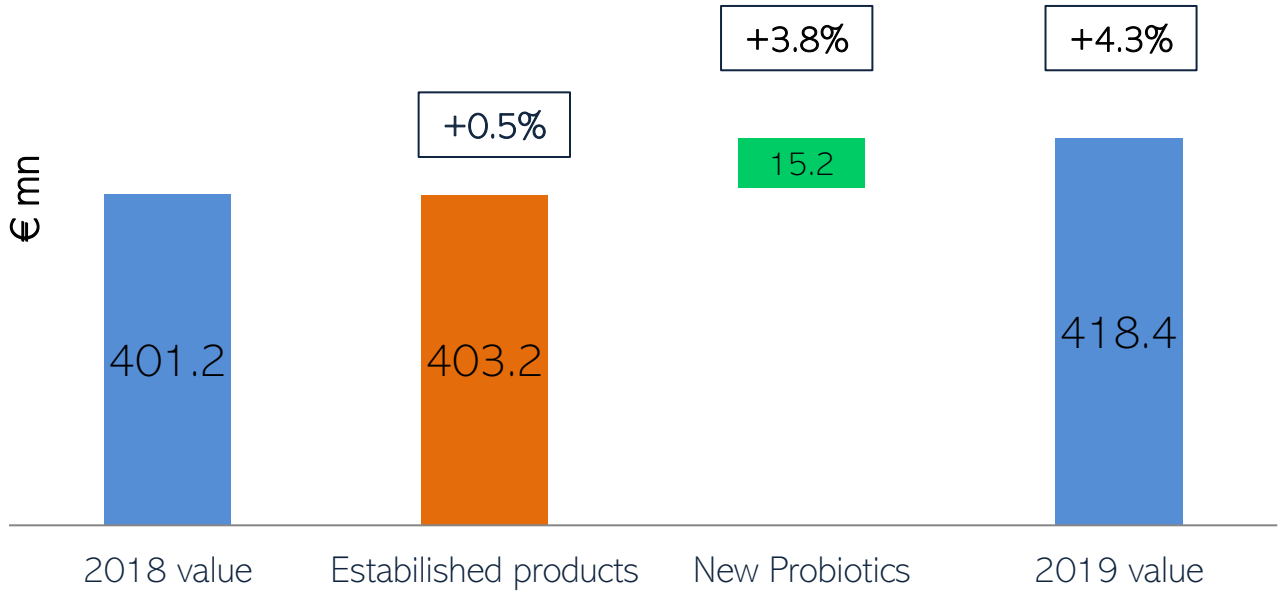
Innovation, in Response to Specific Health Needs, is the Key of the Italian Probiotics Market growth

new probiotics launch represent 88% of the 2018-2019 market's growth



Source: IQVIA Multichannel View data processing, MAT December 2019

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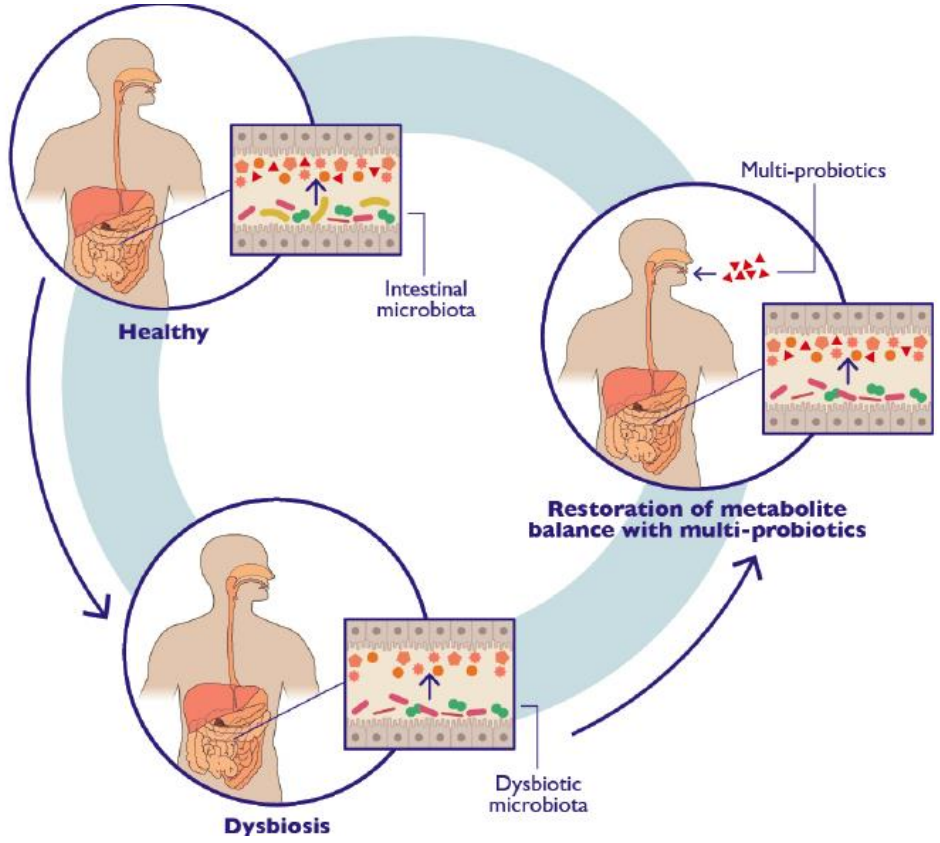
IAP - Planned Pilot Industrial Actions in The Microbiome Nutraceutical System

1. Production of Next Generation Probiotics.
2. Probiotic formulation for human gut microbiota eubiosis and host health
3. Exploit knowledge on microbiome and drug metabolism
4. Exploit the knowledge on microbiome and metabolism of nutraceuticals and xenobiotics
5. Exploit knowledge on microbiome and prevention and progression of some pathologies
6. Exploit the nexus microbiome, enteral nutrition and special nutrition

Probiotic formulation for human gut microbiota eubiosis and host health



Gut microbiota dysbiosis, due to intestinal illnesses and extra-intestinal illnesses, are often treated with the administration of probiotics, prebiotics, and synbiotics. Therapies based on multi-probiotics application could ensure a stronger and long-lasting rebalancing effects

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Probiotic formulation for human gut microbiota eubiosis and host health

The planned actions are;

- Demonstrate, by means of omics approaches, that bacterial consortia can better treat human gut microbiota dysbiosis, (TRL 4).

-Identify the most effective consortia, and formulate oral multi-probiotics combinations resistant to the gastric environment and able to ensure a more efficient microbiota modulation.

-Address and overcome regulatory issues & Strengthen the EFSA engagement with relevant stakeholders so that all parties have a clear understanding of precisely what documentation is required for approval of probiotics (and next generation probiotics) for commercial sale ;

Probiotic formulation for human gut microbiota eubiosis and host health

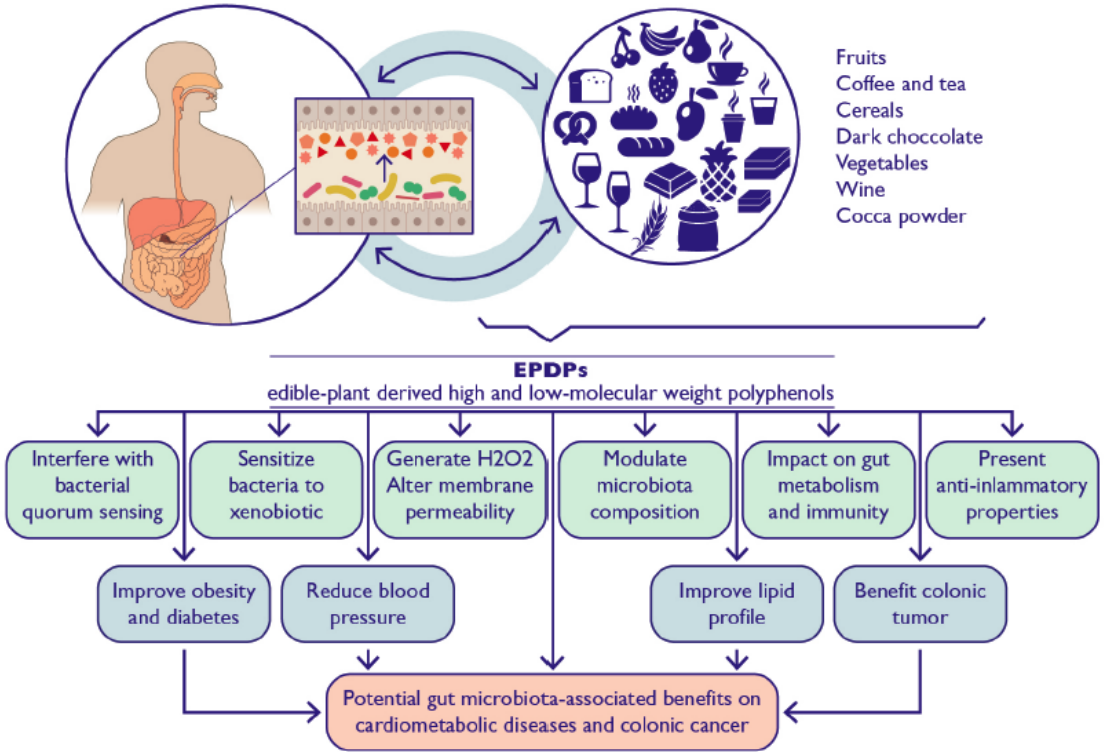
In 2009 EFSA declared «Increasing the number of any groups of bacteria is not in itself considered as beneficial. The Panel considers that no evidence has been provided that ….. enhance levels of beneficial microflora are beneficial to human health»

To date, no health claim on probiotics has received a favourable EFSA assessment and no health claims on probiotics have been authorized

To date there isn't a formal harmonized European approach for the use of the term probiotic on labelling and commercial communications

As declared in the Position Paper EHPM, IPA and EDA – 2017 "Urges EU Member States to find a viable solution within the EU Single Market that would allow the probiotic industry to use a generic, traditional denomination that meaningfully expresses the nature of these foodstuffs and is recognised and used widely around the world".

Microbiome and metabolism of nutraceuticals and xenobiotics



Edible-plant derived high and low-molecular weight polyphenols (EPDPs) represent an emerging group of bioactive compounds that seems to prevent diseases by properly interacting with intestinal microbiota.
In particular, the intestinal microbiota seems to regulate the metabolism and bioavailability of EPDPs, while EPDPs regulated the microbiome metabolism and its effects

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Microbiome and metabolism of nutraceuticals and xenobiotics

Planned actions (TRL: 4)

- Perform Standardized test of well characterized extracts, in simulated human gut microbiota models to study fermentation, biotransformation of the standardized extracts and the metabolomic profiling of products.
- Compare standardized extracts and their fermentation metabolites for their ability to :

a) impact on cross the intestinal barrier,
b) interact with probiotics,
c) affect the microbiota diversity and impact on cellular activation and epigenetics.

-Setting-up of formulative technologies for optimizing intestinal targeting and distribution of major polyphenols.

- Pilot pharmacokinetic studies in human volunteers

The nexus Microbiome, Enteral Nutrition and Special Nutrition

Food for Special Medical Purposes (FSMP) are intended for the exclusive or partial feeding of people whose nutritional requirements cannot be met by normal foods. Some of them, in particular those for oral nutritional supplements and artificial enteral nutrition, are not sufficiently recognized as relevant for their non-pharmacological therapeutic role.

The planned actions are (TRL: 4) :

→ Create new know how on how the microbiota restores with and without interference of nutrition

→ Develop targeted approaches with probiotics or other nutritional solutions, to restore the microbiota and prevent inflammation and infections during a patient's recovery, allowing therapeutic diets helping drugs to be more effective in their therapeutic role.

Thank you

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