



www.creabio-ra.com



BioTuesday - 2 Juillet 2013

Frédéric Mistretta

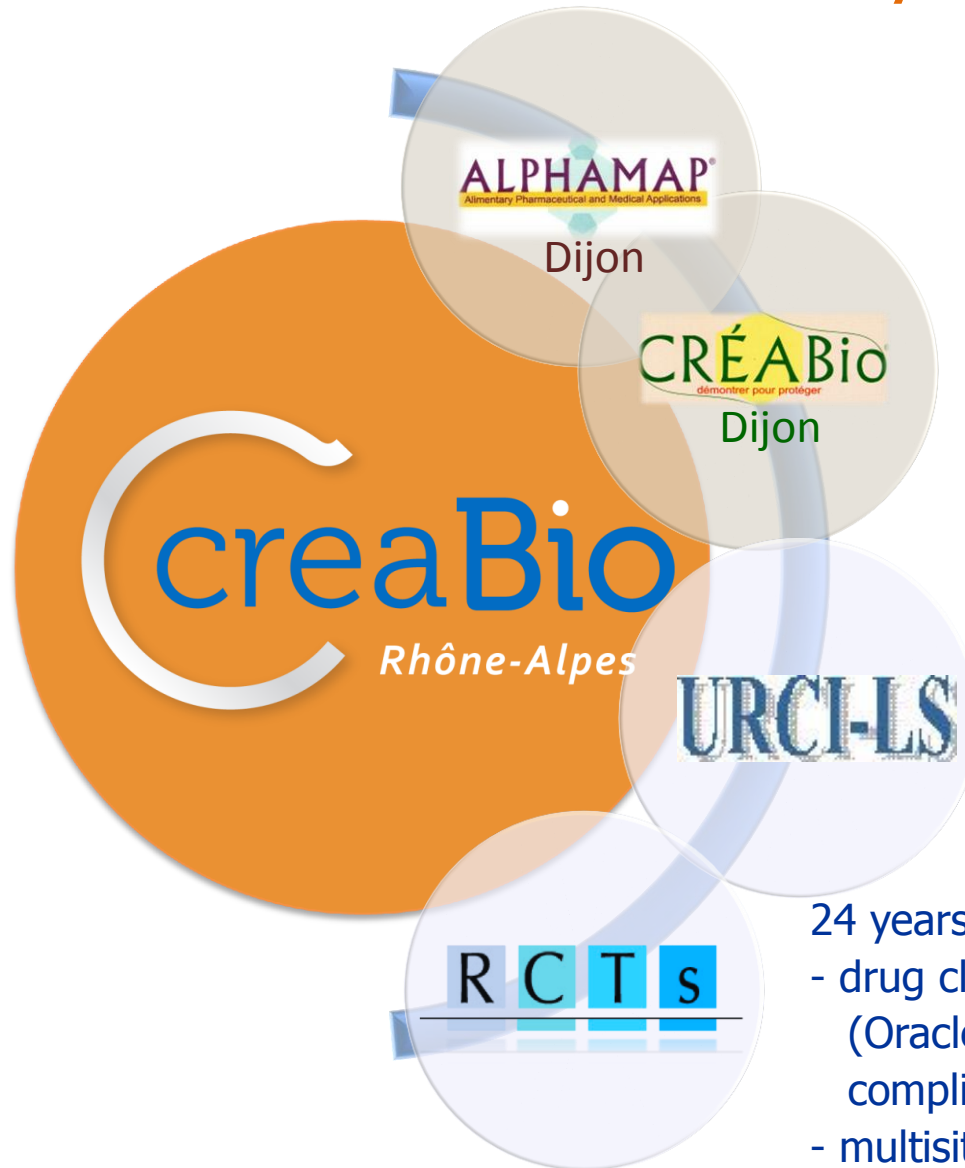
Directeur Général



From Medical Sciences to High Value Health Products



History



15 years experience in clinical development of dietary supplements and nutraceutical products and in medical device for drug delivery in various therapeutic classes

10 years experience in skin immunology, skin allergy and in clinical research in dermo-cosmetology in healthy volunteers

24 years experience in:

- drug clinical trial as a CRO, in biometry (Oracle / SAS softwares, eCRF compliant to 21CFR part 11),
- multisite clinical trials across Europe

Board of directors / Co-founders



[Dr. Philippe E. Laurent](#)

MD, PhD

Chairman of the board of Directors



[Frédéric Mistretta](#)

CEO & Director of Clinical Research



[Dr. Catherine Goujon-Henry](#)

MD

Director of Dermatology & Cosmetology studies



[Pr. Jean François Nicolas](#)

MD, PhD

Director of Allergology & Clinical Immunology studies



[Pr. Marc Fantino](#)

MD, PhD

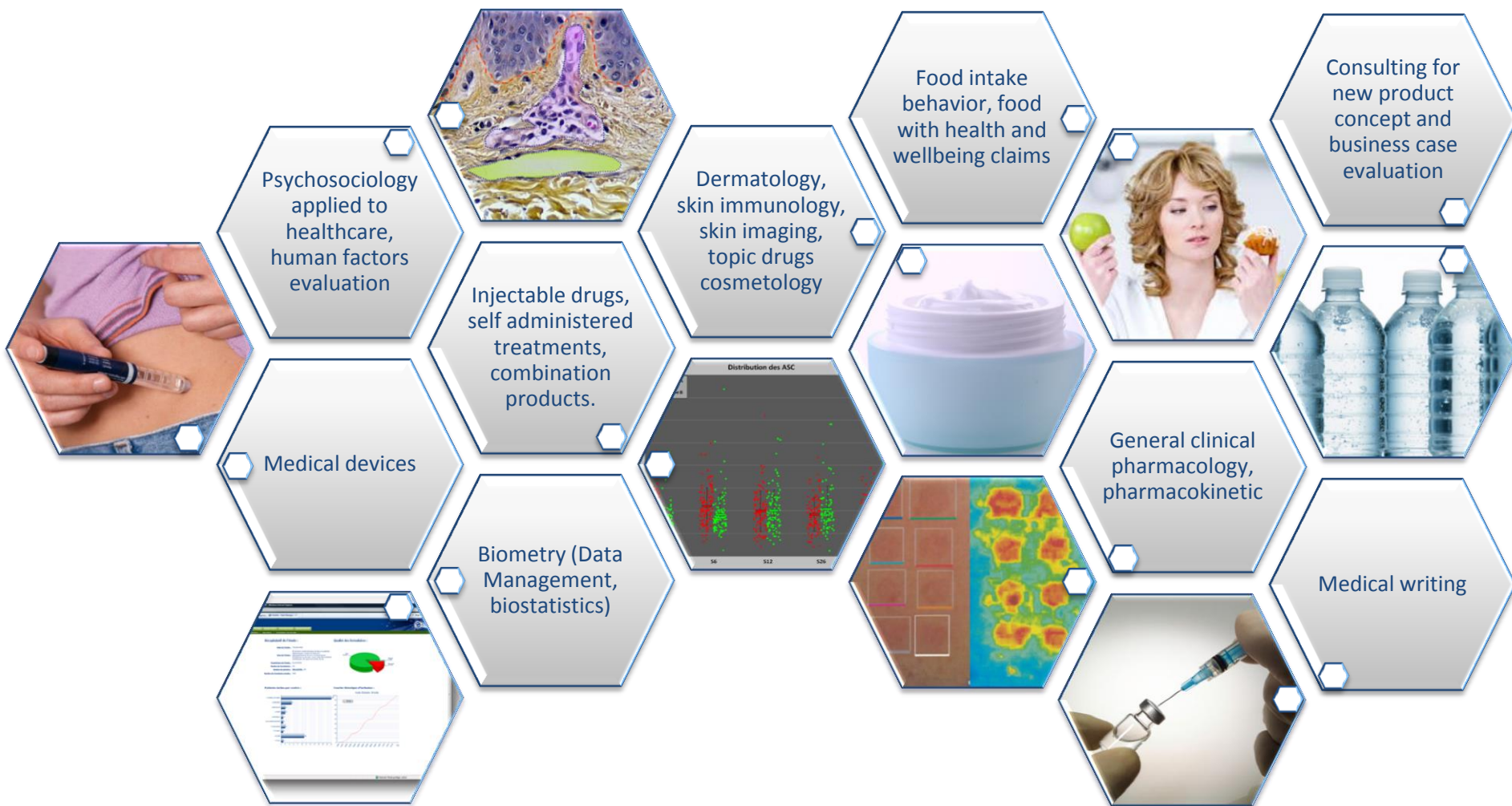
Director of Nutraceutical studies



[Yves Alamercery](#)

Financial & Administrative Director

Our Main Areas of Expertise



Three Business Units



Consulting

Where am I?

Concept phase

Development phase

Commercial phase

What do I need?

Customer /
user unmet
needs and
requirements

Business
case

Proof of
concept

Definition
phase

Pre-industrial
development

Industrial
development
and
registration

Post-marketing
surveillance

- Field studies on customer and user
- Customer and user willingness / need to change practices
- Market constraint model analysis

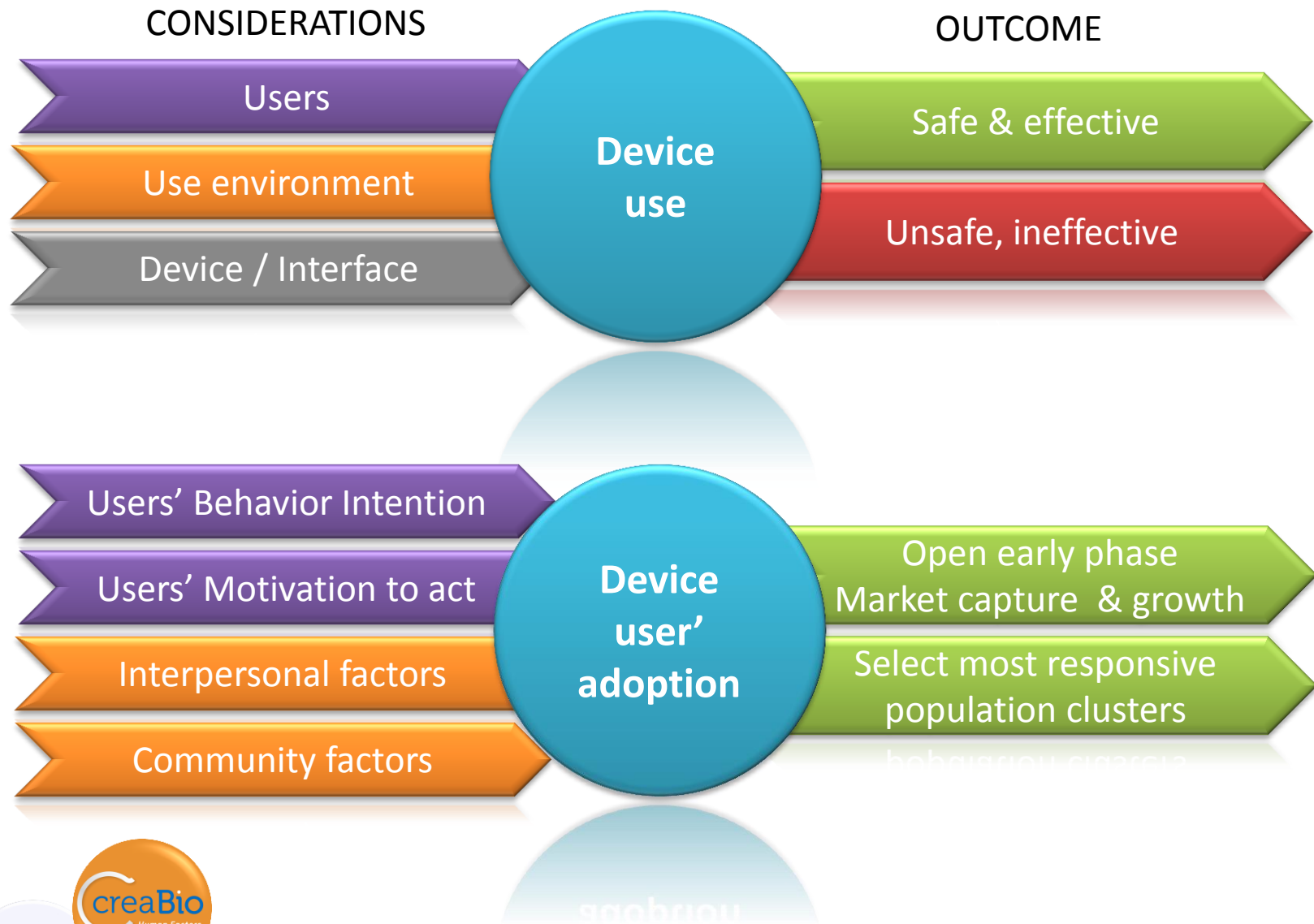
- Anticipated Medical / clinical value proposition
- Market cost acceptance
- Market size and value
- Porter model / SWOT analysis
- Customer profile
- Market access constraint
- Capability gap analysis
- IP situation
- High level financial projection

- Non clinical and clinical plan for proof of concept
- Human Factor Analysis

- Non-clinical development plan
- Clinical development plan
- Regulatory and standard compliance plan
- Health and hazard risk management plan

- Post-market evaluation
- Health and hazard risk assessment

Evaluation principles



Clinical Research: Topical Drugs

Domains:

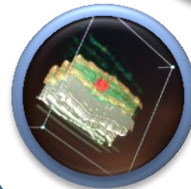
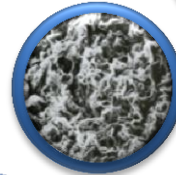
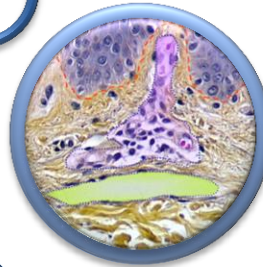
- non steroidal anti-inflammatory
- antibiotic
- wound healing drugs corticosteroids
- immuno modulating drugs
- retinoids
- menotridazole

Type of studies:

- safety on healthy volunteers or patients
- efficacy in healthy volunteers or patients

CreaBio unique competencies:

- Skin imaging techniques : high frequency ultrasounds, confocal in-vivo microscopy, X-ray, CT Scan
- Skin immunology and immune response from skin biopsy with immune cells phenotype analysis and cytokine/chemokine expression



Clinical Research: Medical Devices

Medical Devices Domains: vaccine and self-administration of injectable drugs

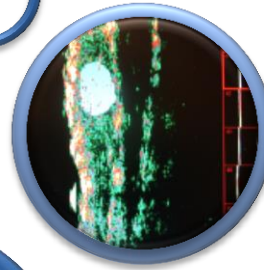
- Injectable drug delivery systems (prefilled and not prefilled) IV, SC and intra-organ infusion systems
- Skin and mucosa contact medical devices
- Intradermal, intranasal, intramuscular delivery systems

Type of studies

- Clinical studies in Healthy Volunteers evaluating medical device efficacy and safety
- Simulated study evaluating human factors, usability, user's acceptance, preference in targeted population

CreaBio unique competencies

- Skin imaging techniques : high frequency ultrasounds, confocal in-vivo microscopy, X-ray CT Scan
- Skin immunology and immune response
- Ergonomics, user's learning and education
- User's attitude and emotion analysis and psycho sociologic evaluation of user behavior
- Subject's perceived pain, sensorial perceptions



Clinical Research: Cosmetology

Cosmetology Domains:

- moisturizing cream
- cleansing cream
- shampoo
- deodorant perfumes
- soap
- make-up
- anti-wrinkle products

Type of studies:

- Safety on healthy volunteers : patch test, open test, repeated open test, test in use, etc.
- Efficacy in healthy volunteers

CreaBio unique competencies:

- Possibility to differentiate allergy from irritation (skin biopsy and immune cells phenotype analysis)
- Immuno-cosmetology : skin biomarkers of photoageing



Clinical Research: Nutrition & food

Nutrition Domains:

- Nutritional and health claims
- Functional foods
 - Macro and micronutrients
 - Vitamins and minerals
- Antioxidants
- Food supplements
- Fiber and allergy
- Beverage

Type of studies:

- Satiation and satiety
- Body weight management
- Metabolic assessments
- Body composition (DEXA)
- Food consumption surveys
- Sensory evaluation
- Food preference
- Pharmacokinetic
- Glycaemic index
- Energy expenditure

CreaBio unique competencies:

- Measure of body composition
- Metabolic and nutritional check-up
- Continuous blood sampling for pharmacokinetics studies



Clinical Research: Allergy

Allergy Domains:

- Drug allergy, food allergy, cosmetic product allergy, new chemical entities allergy, latex allergy, industrial process agent allergy
- Urticaria, contact dermatitis, skin adverse effects of drugs & cosmetics
- Gastro-intestinal food allergy

Type of studies:

- In-vitro introduction of hypersensitivity on human skin immuno-competent cells
- Clinical studies in Healthy Volunteers and allergic patients

CreaBio unique competencies:

- Skin imaging techniques : high frequency ultrasounds, confocal in-vivo microscopy, X-ray CT Scanning
- Skin immunology and immune response from skin biopsy with immune cells phenotype analysis and cytokine/chemokine expression

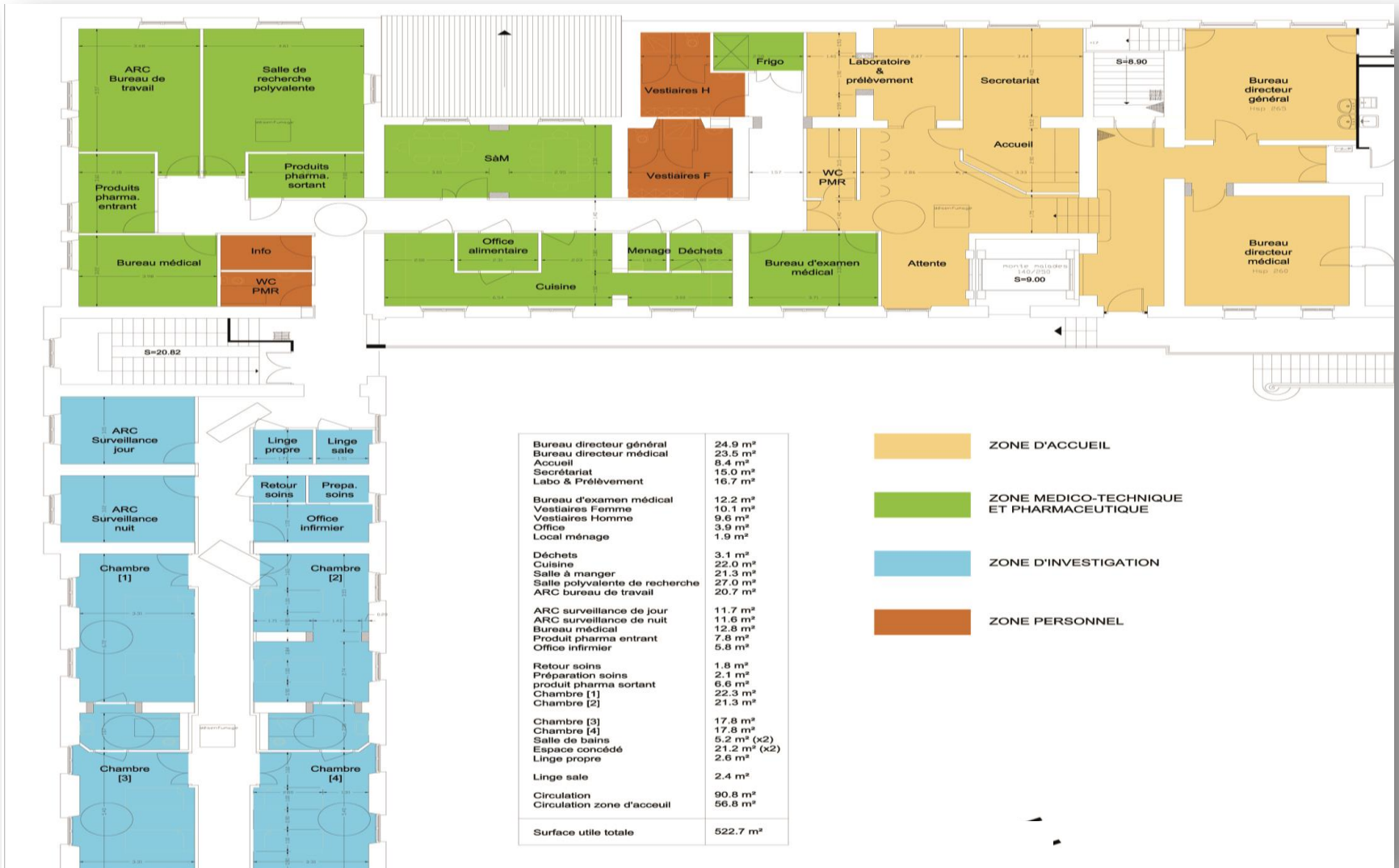


Our Clinical Research Center

- Located inside Givors hospital: 600 m² entirely renovated and dedicated to CreaBio clinical trials.
- Includes a nutrition research laboratory, biological sampling equipment, several medical examination rooms, a pharmacy and 4 rooms for the volunteers (total: 8 beds).



Our Clinical Research Center





www.creabio-ra.com



Your Contacts

Frédéric Mistretta

Co-founder & CEO

Director of Clinical Research

- ☎ +33 (0)4 37 45 17 35
- ✉ frederic.mistretta@creabio-ra.com

Philippe E. Laurent, MD, PhD

Co-founder & President

Consulting Clinical Research – Medical
Devices, Human Factors

- ☎ +33 (0)6 82 81 51 72
- ✉ philippe.e.laurent@creabio-ra.com



From Medical Sciences to High Value Health Products

