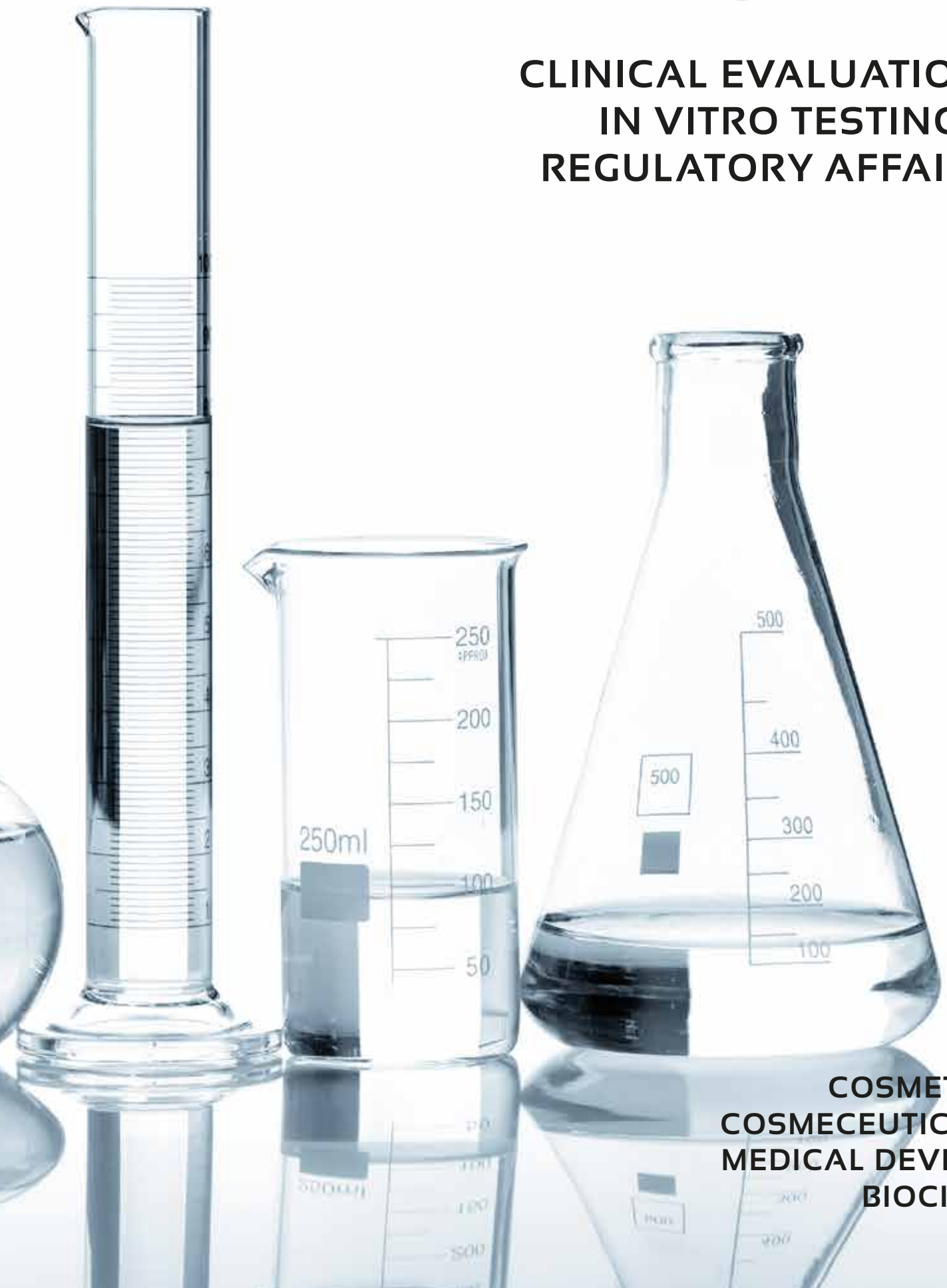


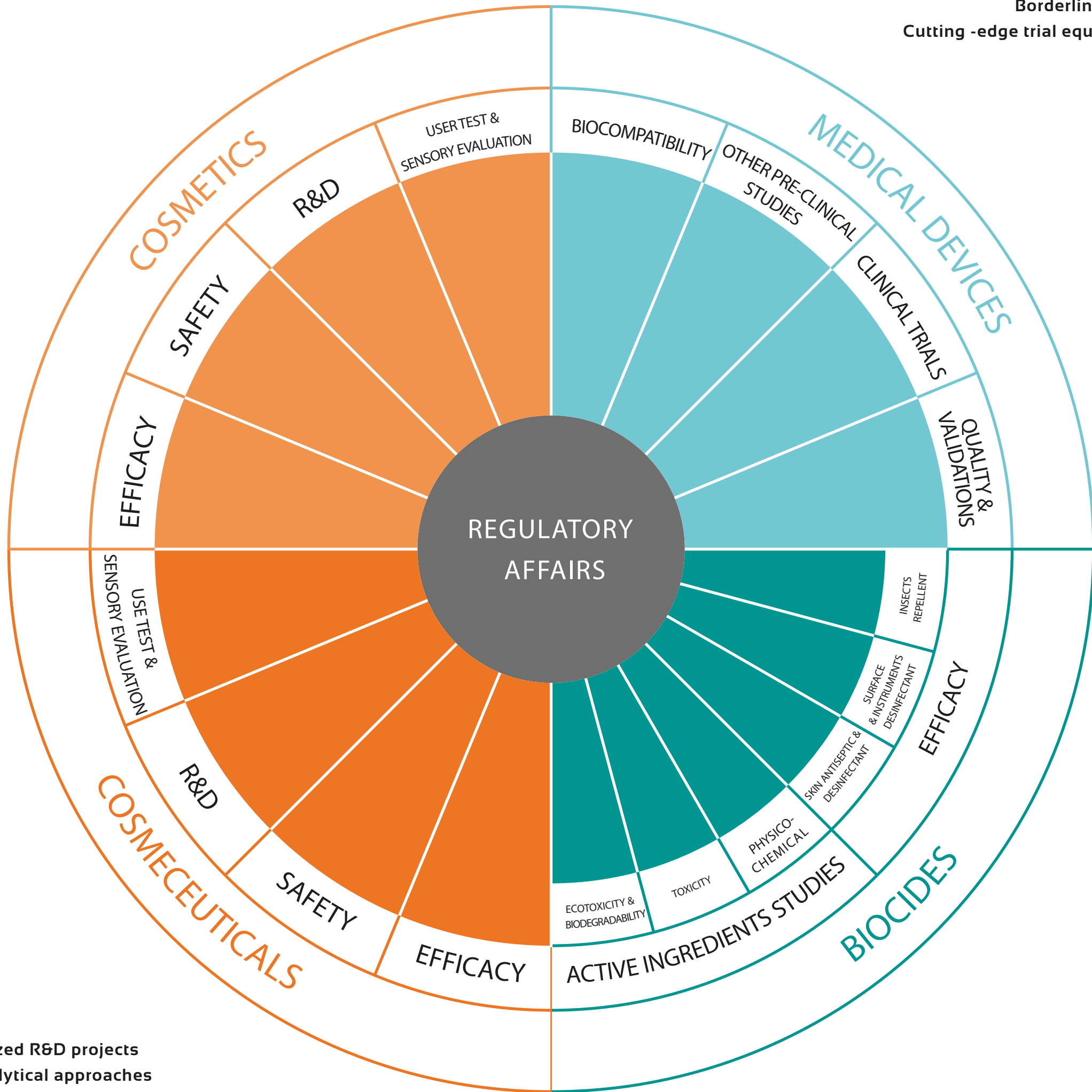


**CLINICAL EVALUATION,
IN VITRO TESTING &
REGULATORY AFFAIRS**



**COSMETICS
COSMECEUTICALS
MEDICAL DEVICES
BIOCIDES**

SCIENTIFIC TESTING & SERVICES



Borderline claims
Cutting -edge trial equipments

Customized R&D projects
New analytical approaches
Experimental tests design



COSMETICS & COSMECEUTICALS

Dinamic & profesional Regulatory
Department



Medical specialists approval
Multidisciplinary expertise
Complete analytical spectrum

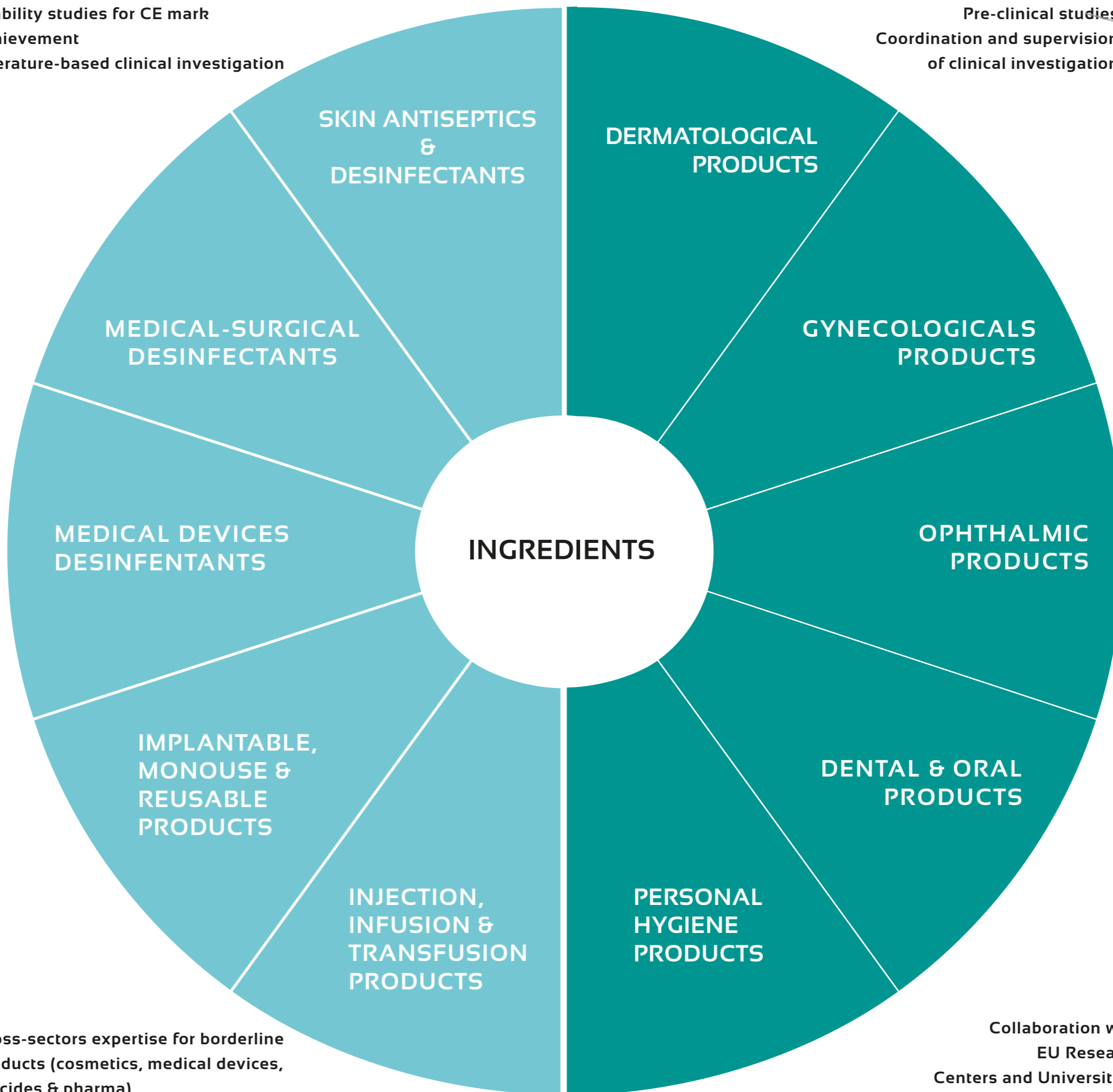
Support for the full compliance with
European Regulation 1223/2009
From raw material to final product

Wide range of volunteers panels:
Racial specificity
From 3-month to 3-year babies
All type of dermatological characteristics

MEDICAL DEVICES & BIOCIDES

Viability studies for CE mark achievement
Literature-based clinical investigation

Pre-clinical studies
Coordination and supervision of clinical investigation



Cross-sectors expertise for borderline products (cosmetics, medical devices, biocides & pharma)

Collaboration with EU Research Centers and Universities.



COSMETICS & COSMECEUTICALS

	IN VIVO EFFICACY		IN VITRO EFFICACY	IN VIVO SAFETY	IN VITRO SAFETY
FACE CARE	Moisturizing effect (hydration kinetics) Anti-wrinkles Anti-aging effect Firming and elasticity effect Tensor / lifting effect Effect on the skin barrier function Peeling/Exfoliating effect Regenerating effect	Sebo-regulating effect Matifying effect Astringent effect Comedolitic effect Whitening effect Depigmenting effect Non-comedogenicity		Antioxidant efficacy (ROS, biochemical methods) Anti-wrinkles Anti-ageing Whitening effect Sunscreen effect after solar radiation Photoaging efficacy after solar radiation	Patch Test- Single Closed Application Open Test Repeated Open Application Hypoallergenicity (HRIPT)
BODY CARE	Moisturizing effect (hydration kinetics) Firming and elasticity effect Anti-Cellulitis Effect Reducing Effect	Anti-stretchmarks effectiveness Depilatory effectiveness Tanning accelerating effect Tanning effect maintenance		Antioxidant efficacy (ROS, biochemical methods) Collagen and elastin synthesis stimulation Inhibition of collagenase and elastase	
SUNSCREEN & SOLAR PROTECTION	Sun Protection Factor SPF (ISO 24444; FDA) Water Resitance Very Water Resistance (Colipa 2005) UVA FP evaluation – PPD (ISO 24442) Sweat resistance	Low adherence to the sand Tanning booster Efficacy against redness after solar radiation Non-comedogenicity		UVA PF evaluation (ISO 24443; Colipa 2011) Critical wavelength evaluation Water and very Water Resistance Ratio UV-A/UV-B. Boots Star rating 2011 Antioxidant efficacy (ROS, biochemical methods) Photostability and high photostability evaluation	
ORAL CARE	Tooth whitening Effective against tooth sensitivity Efficacy against dental plaque Efficacy against halitosis			Efficacy against biofilm	
HAIR CARE	Anti dandruff activity Sebo-regulating effect Anti-hair loss effect Hair growth effect	Gloss effect Color maintenance Eyelashes strengthener		Capillary -fortress (keratin synthesis) Hair growth (cell proliferation)	
MAKE UP	Long lasting make up Coverage effect make up Matt effect make up Waterproof eyelash mascara Eyelash mascara volume/Extra-volume effect Eyelash mascara lengthening effect Eyelash mascara curling effect	Lipstick gloss effect Lipstick long-lasting effect Lipstick volume effect Lipstick non transferable effect Lip repair effect Non-comedogenicity Eyelashes strengthener			
HYGIENE & PERSONAL CARE	Tooth whitening (clinical use) Peeling effect	Reducing and Anti-Cellulite Effect (transdermal patches)		Maintains Natural flora	
BABIES & KIDS PRODUCTS	Moisturizing effect Effect on the skin barrier function	Prevention and protection against irritation after diapers use		Shooting effect	
DEODORANTS	Deodorant Effect Antiperspirant effect No marks on textiles				
BORDERLINE COSMETIC PRODUCTS	Products for atopic skin Intimate hygiene products Products for acne tendency skin				
					Non-irritating (skin, eyes & mucose) Not Phototoxic (OECD 432) Not Citotoxic (ISO 10993) Skin Absorption / Penetration
					Use test / sensory evaluation
					Stability studies
					Microbiological studies (Challenge test)

BIOCOMPATIBILITY

- Cytotoxicity
- Sensitization
- Irritation (skin, eyes, mucose)
- Intracutaneous reactivity
- Acute Systemic Toxicity (Subacute, Subchronic and Chronic Toxicity)
- Genetic Toxicology (in vitro and in vivo)
- Implantation
- Implantation in Combination with Systemic Toxicity
- Hemocompatibility
- Pyrogenicity

COMPLEMENTARY PRECLINICAL TRIALS

- Stability studies (accelerated, shelf life, in use, etc.)
- Antimicrobial efficacy studies of preservative system
- Efficacy studies for medical devices disinfectants
- Efficacy studies with cell culture
- Bacterial/bacteriostatic activity of surfaces, substances and formulations

QUALITY CONTROL AND VALIDATION

- Microbiological control of product (bioburden, sterility, LAL test)
- Microbiological control of processing environment
- Processing water control
- Control of ethylene oxide residues
- Control of chemical parameters (HPLC, GC-MS, ICP-MS)
- Heavy metals

BIOCIDES

Type of products: Healthy skin antiseptics
Instrumental disinfectants
Surface disinfectants
Insect repellents

Type of studies: Efficacy (in suspension and volunteers) of
Bactericidal activity
Eusticidal activity
Virucidal activity

Toxicity

- Skin corrosion (in vitro)
- Skin irritation (in vitro – in vivo)
- Eye irritation in vitro
- Skin sensitization (in vitro – in vivo)
- Mutagenicity (Ames Test)
- Citogenetic testing in mammalian cells
- Gene mutation test in mammalian cells
- Acute toxicity
- Acute oral toxicity
- Acute dermal toxicity
- Acute inhalation toxicity
- Repeated dose toxicity
- Subchronic toxicity
- Chronic Toxicity

Ecotoxicity & Biodegradability

- Fish acute toxicity test
- Fish chronic toxicity test
- Bioaccumulation in fishes
- Long term toxicity

Physico-chemical properties

- Identification of substances: spectroscopy
- Identification of substances: chromatography
- Viscosity

COSMETICS & COSMECEUTICALS

The EU Cosmetic Regulation (EC) no. 1223/2009 was adopted in 2009 and entered into force in July 2013. To fully comply with this obligatory regulation, we support our clients with:

Preparation or revision of the Product Information File (PIF)

Revision and translation of labelling

Review and integration of the technical and administrative documentation provided by the company

Elaboration of the Material Safety Data Sheets (MSDS)

Preparation and signature of the safety assessment of cosmetic products

Entering data into the European Cosmetic Products Notification Portal (CPNP)

MEDICAL DEVICES & BIOCIDES

At Zurko Research we offer our clients all the necessary support for their medical devices, from all risk classes (I, IIa, IIb, III):

CE Marking
we elaborate the complete Technical File and Risk Management documentation.

Licences
We elaborate and manage all type of documentation and procedure for medical device Activity License obtainment.

ISO 13485
We support our client in the establishment and review of the Quality Management System required for medical devices.

Coordination and supervision of clinical trials
At Zurko Research, we guide manufacturers of Medical Devices through the entire process, step by step:

Application to national competent authority (AEMPS)

Application to the Clinical Research Ethics Committee (CREC)

Identification of the Research Centre (public or private)

Coordination of multi-centre research

Support with the drawing up of the clinical research Plan (PIC)

Presentation and defense of the project before the CREC

Support with the selection of patients panel

Trial supervision

Assistance with the drafting of the final report

BIOCIDES

Biocidal products are subject to different regulations depending on the intended purpose indicated in the labeling and instructions for use of the products.

In addition to conducting the necessary tests, Zurko is responsible for the preparation of all regulatory procedures for the commercialization of:

Antiseptics for healthy skin, including those for pre-operative surgical area

Desinfectants for environment and surface used in medical and surgical areas, not in direct contact with the patient.



WHO WE ARE

ZURKO RESEARCH, created in 2005, is a centre for clinical and in vitro evaluation, testing the safety and efficacy of cosmetic and cosmeceutical products, as well as medical devices.

We are committed to the five fundamental principles that drive our business model:

- Personalized service and fluent communication with our clients;
- Optimum quality throughout the work process; speed of response;
- Tailor- made solutions for innovative statements and personalized advice.

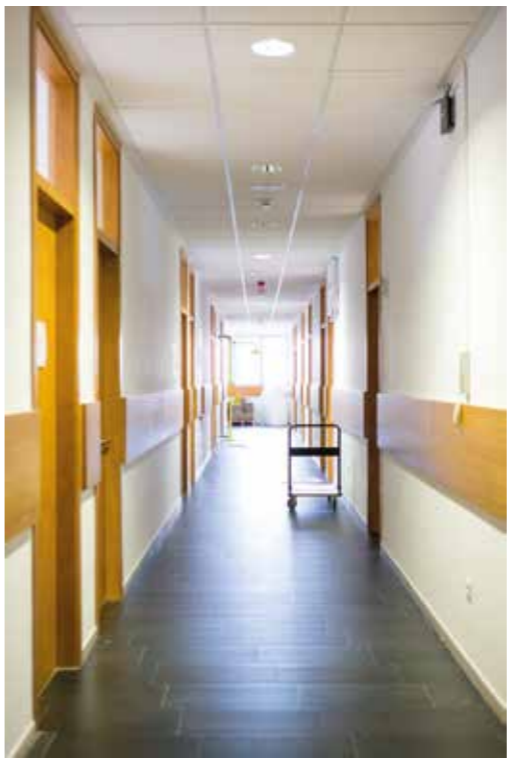
We count on experienced renowned professionals, as well as a wide clinical team of specialists (dermatologists, ophthalmologists, pediatricians, gynecologists, stomatologists).

The Quality Department designs and develops all the studies in accordance with the principles of the Good Clinical Practices (GCP) and Good Laboratory Practices (GPL).



MADRID - CLINICAL TRIALS

ALBACETE - IN VITRO STUDIES



FACILITIES

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Efficiency is our business

