

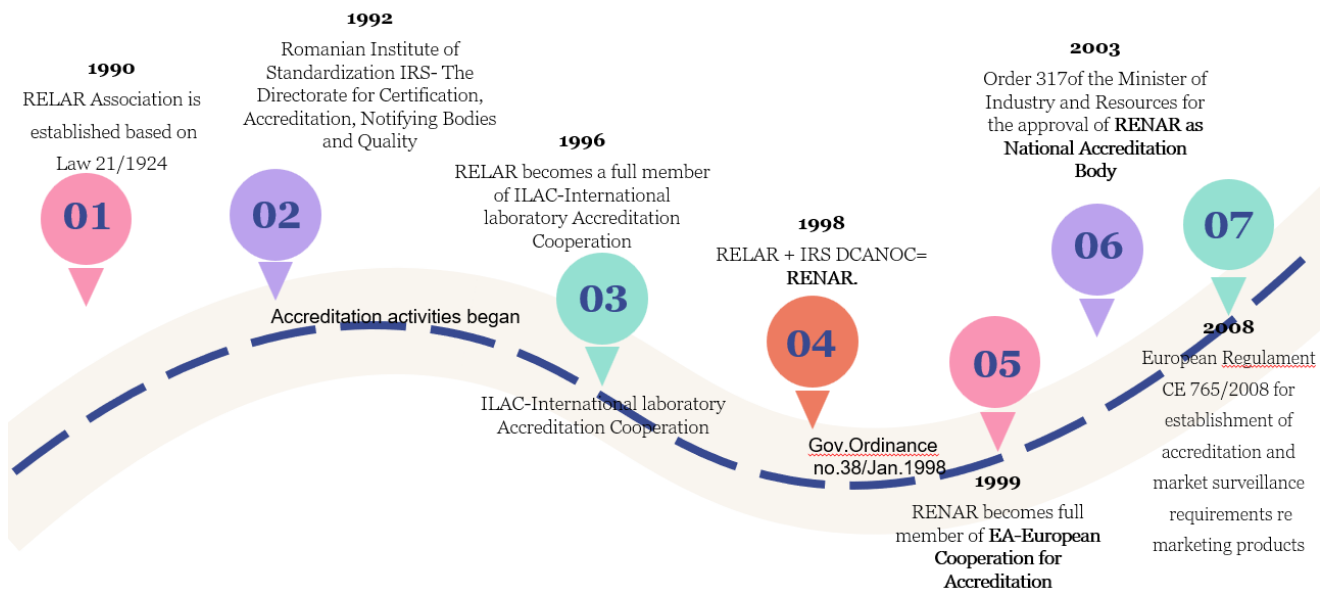
# Accreditation of medical laboratories in Romania.

**Dr. Cristina Florescu-Moraid, MSc, EuSpLM**

CEO Avantyo Institute of Clinical Research

CEO and Co-Founder Camina Medical Experts

## Short History Roadmap



## Laboratory Accreditation Body in Romania

RENAR = Accreditation Association in Romania

RENAR = non-governmental, non-profit organization, established based on the provision of Law 21/1924 with subsequent amendments, its legal personality has been recognized by Civil Sentence no.1966/1990 of the Court of Bucharest

RENAR = officially recognized as a UNIQUE national accreditation body and operates under Ministry of Economy

RENAR has an NGO structure, as in most developed countries, because the body must be independent and operate on a non-profit basis.

## Fields of RENAR accreditation

The association can accredit the following bodies:

- a) testing / calibration laboratories;
- b) medical laboratories;

- c) inspection bodies in the field of conformity assessment;
- d) product conformity certification bodies;
- e) management systems certification bodies;
- f) person certification bodies;
- g) providers of competency tests;
- h) other bodies, with priority for fields that will be established by the associations of cooperation of accreditation bodies at European and global level

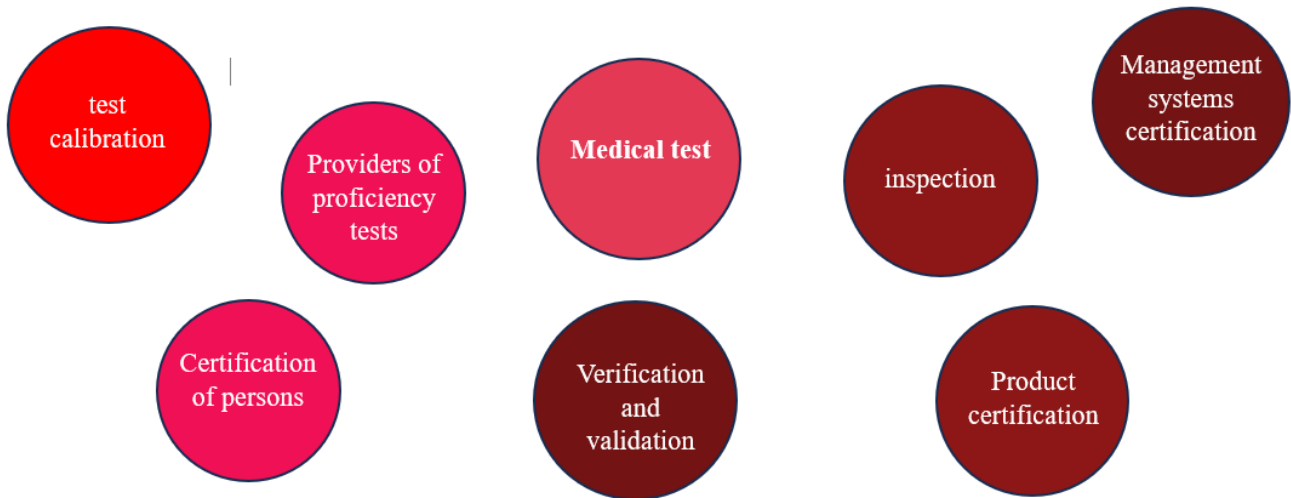
### **Organization of RENAR**

The members of the Association are grouped **Colleges**:

- A. **The College of accredited bodies**, which includes representatives of accredited bodies by RENAR, as well as their non-patrimonial representative associations;
- B. **The College of beneficiaries**, which includes representatives of legal entities that benefit from the services of accredited bodies, such as: economic agents, including small and medium enterprises, employers' organizations, chambers of commerce and industry, financial-banking and insurance organizations, professional associations, as well as others also, including their non-patrimonial associations;
- C. **The consumers' College**, which represents the interests of civil society, which benefits indirectly by accredited conformity assessment services, includes representatives' organizations without patrimonial purpose for the protection of consumers' interests, for environmental protection, in the field of quality, as well as of organizations in the field of education, research-development, health and the like;
- D. **The College of Authorities**, which includes the representatives of the central public authorities and local,

The colleges meet in full at least **once a year**.

## Activities for RENAR competency

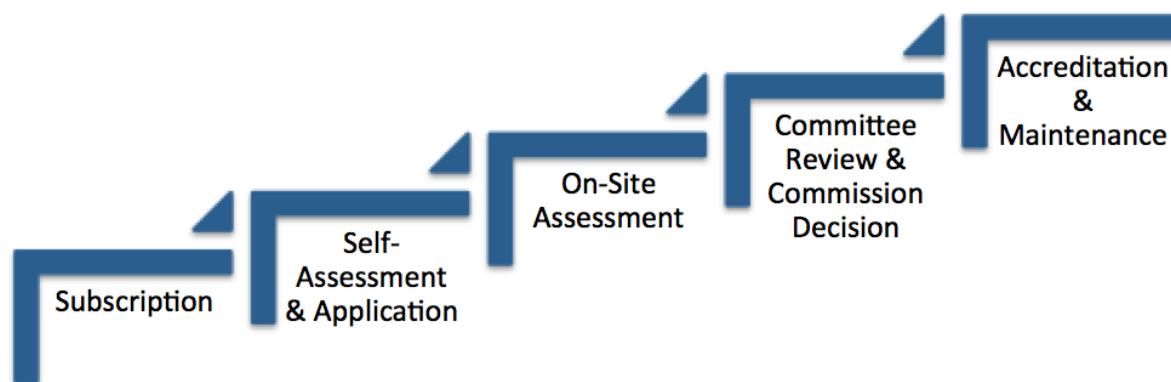


RENAR accredits conformity assessment bodies in the regulated field, based on European Regulations and Directives.

### Renar's REGULATION FOR ACCREDITATION – STEPS

1. Submission of the request for accreditation
2. Analysis of the request for accreditation
3. Preliminary visit- not mandatory
4. Acceptance/non-acceptance of the request for accreditation
5. Contracting and nominating of evaluation team of RENAR
6. Analysis of documented information (documents and records)
7. Evaluation plan
8. On-site assessment
9. Evaluation by assistance (RENAR conducts assisted assessments to gather objective evidence, through observation, regarding the competence of the OEC to carry out the activities that are included in the field for which a accreditation requested/ is accredited)
10. Follow-up assessment (In the situation where, following the assessment, non-conformities were identified, the OEC transmits to RENAR action plan and evidence of resolution of non-conformities)
11. Evaluation reporting
12. ACCREDITATION DECISION- Certificate of accreditation( RO & EN )

Accreditation cycle stands for 4 years



## ACCREDITATION PROCESS

The accreditation process involves several evaluation stages.

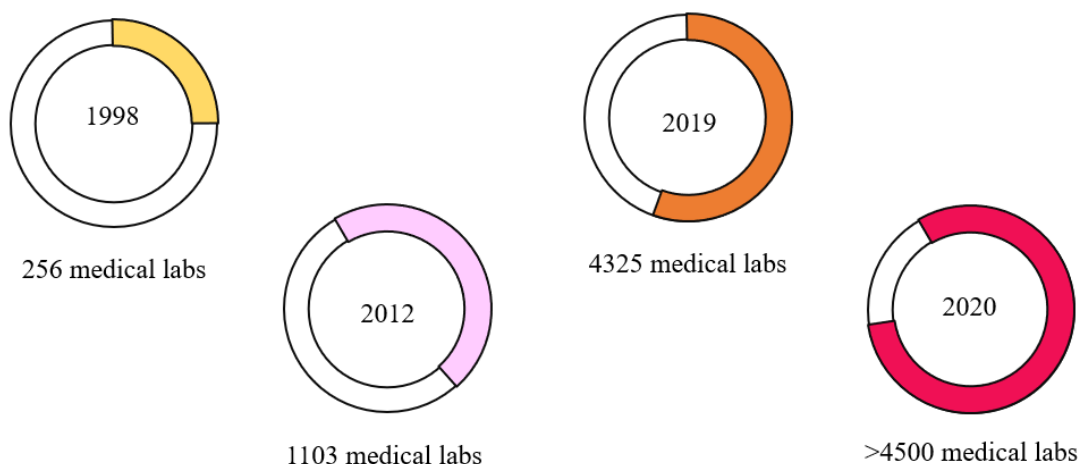
Each chapter has requirements that need to be checked – the team checks the requirements, analyzes the reagent stocks and the IT system to perform the process.

The appendix of the laboratory's accreditation certificate has many pages and for each parameter there must be evidence, the policy that must be respected.

After accreditation, the laboratory enters the supervision process, which is carried out regularly.

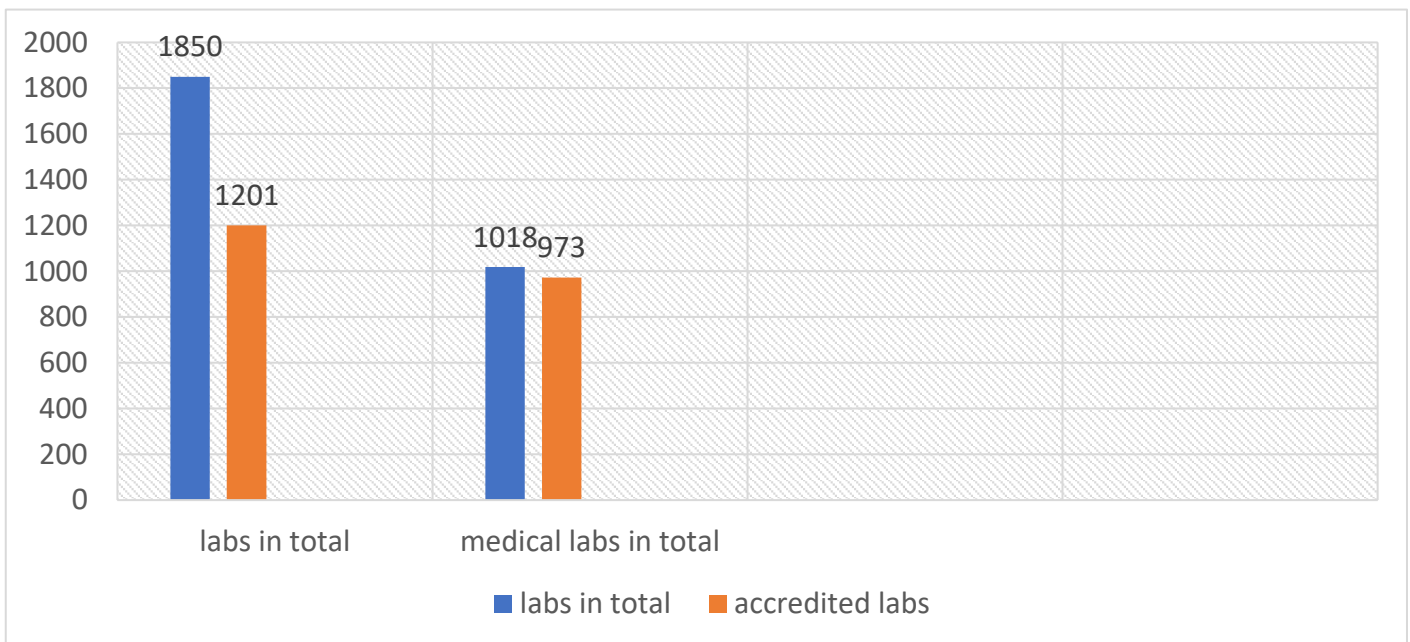
All this process must be carried out **within a year**, but as a rule, the evaluation is carried out, thanks to the mobilization of RENAR specialists, in just a few months.

## Evolution of number of medical labs in Romania



Over 2000 existing private medical labs in Romania, >510 located in Bucharest.

## Accredited labs on Romanian market



SR EN ISO 15189:2013

### Benefits of laboratory accreditation

- Medical analyzes and investigations are extremely important in establishing any diagnosis, and obtaining the correct results proves to be essential for the life and health of patients.
- An accredited laboratory provides assurance that medical testing laboratories and a wide range of healthcare devices meet the highest standards and operate at their best parameters.
- Analyses performed in an accredited laboratory give confidence that they are performed according to the requirements of the standard.

The national regulatory body has a fundamental role: it assesses and certifies the conformity of procedures and equipment.

Everything starts from the European legislation- EC regulation no. 765/2008 of the European Parliament and the Council, establishes the EU policy in the field of accreditation and states that *“single national accreditation body operates in each EU state, which is periodically evaluated”*

In Romania, this is the National Accreditation Body RENAR, and any certificate issued is recognized in the EU and internationally.

## **Benefits of laboratory accreditation**

- Accreditation is **mandatory** for those labs who **receive financial resources from CNAS**.
- Many times, citizens request to have their analyzes done by a RENAR laboratory. This means that trust in accreditation is increasingly widespread.
- If an European or Australian citizen comes and does his analysis at an accredited laboratory, the report is recognized all over the world!

Q: WHAT DOES MEETING ALL STANDARDS ENTAIL?

A: A lot of **rigor**.

**Benefit from guarantee of SAFE AND CORRECT RESULTS!**