EDITORIAL

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The Colorectal Cancer Screening Program in Romania - ROCCAS - is Ready for the Implementation at National Level

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Colorectal cancer (CRC) is the third cause of cancer-related death worldwide [1]. Its' global incidence is predicted to increase with 80% by 2040, and the highest mortality rates are reported in Central-Eastern Europe (20.2 per 100 000) [2]. Although specific data for Romania are scarce, in 2020 more than six thousand deaths were caused by CRC, and almost thirteen thousand new cases were diagnosed, the majority in late stages [1]. Colorectal cancer is nevertheless a largely preventable malignancy and curable if diagnosed at early stages [3]. Robust screening programs enable the detection and the removal of precancerous lesions and could decrease CRC related mortality with up to 60% [2].

Colorectal cancer screening dates back in early 1970s in Germany where guaiac based fecal occult blood testing (gFOBT) was performed opportunistically [4]. Systematic CRC screening programs were initiated in Europe in the early 2000s [5]. The Council of The European Union (EU) emitted in 2003 the first recommendations on the development and implementation of population-based cancer screening programs across the Member States (2003/878/EC) [6]. The programs should be in accordance to the national laws and best practice European guidelines, based on centralized data systems, monitored regularly, provided by adequately trained personnel, based on fully informed consent, and made available for the target populations across all socioeconomic groups [6]. The strategy recommended for CRC screening included fecal occult blood screening for individuals between 50-74 years, followed by colonoscopy in positives [6]. In 2010, the release of the first EU Cancer Screening Report led to the publication of the first edition of the European Guidelines for quality assurance in CRC screening and diagnosis [7, 8]. It is still in force as of today and offers a uniform framework for CRC screening [7, 8]. Each country may decide on organizing its' screening strategy; however, special emphasis was made on quality control assurance and the need for adequate financial and human resource for implementation [8]. In 2017 when the EU published the second Cancer Screening Report, all the Member States except Bulgaria, the Slovak Republic and Romania had a policy or official recommendation on CRC screening [9]. At that time in Romania mainly "grey"/"wild" testing was performed, especially in the private sector, in symptomatic individuals, and there was no infrastructure for systematic screening. To qualify as a program there should be a public screening policy defining - the screening test, the examination intervals and the target population, and the screening examinations should be financed by public sources (with co-payment possibility) [9]. Organized programs require a higher degree of management involving a policy implementation team at national or regional level [9]. In 2018, the European Commission offered assistance for the initiation of CRC screening in Romania through the Structural Reform Support Program. Members of the Italian Cancer Screening Observatory trained Romanian senior managers, policymakers, endoscopists and pathologists to design a communication campaign and launch screening pilot programs in Romania in line with the European guidelines. As a results, in 2019, ROCCAS – the Romania Colorectal Cancer Screening program was initiated.

ROCCAS is a collaborative project between the Ministry of Health, the National Institute of Public Health, the Society of Gastrointestinal Endoscopy, the Society of Family Doctors and specialists in histopathology and laboratory medicine from Romania (Fig 1). It is financed by the European Social Fund and has a total duration of 60 months until the end of 2023. It is organized in two phases. Phase one is dedicated to the development and implementation at national level of the organizational framework necessary for the initiation of CRC

screening and will be ongoing during the entire duration of the project. In phase two started in 2020, the program has been piloted in 4 of the 8 administrative regions of Romania. The cascade development of the program – starting with a pilot project, followed by pilot extension and subsequent national level roll-out is meant to identify the populational and administrative particularities in CRC screening in our country to allow adaptation of the screening strategy accordingly [10].

The specific objectives of the phase one are the following: establishment of the methodology for CRC screening in Romania, preparation of a training curriculum for CRC screening and its' accreditation, set-up of the national registry for CRC screening, extensive training for all health care providers involved in the program – adequately trained personnel being a prerequisite for a high-quality screening program [11], and information, education, and awareness raising among the target group. In total, 850 medical doctors attended the courses and training sessions within the program until September 2023. Information campaigns were organized for the target group, with family physicians and project-affiliated non-governmental groups playing a crucial part. The Electronic Screening Record System was developed. The four regions selected for program piloting were Southwest, South, Bucharest-Ilfov and Southeast. A screening center was established in each region. They were projected to comprise 200,000 persons eligible for screening of whom minimum 50% shall belong to disadvantaged groups. The target population was defined as individuals aged between 50-74 at standard risk for CRC [8]. The disadvantaged group has a complex definition including – rural area residence, prior institutionalization, homeless, unemployment, disability or in charge of disabled family member, Roma population, narcotics addiction, mono-parental families, domestic violence. The family doctors involved in the program applied a risk questionnaire to identify the eligible population. Individuals with symptoms or at high risk for CRC were referred directly for diagnostic procedures. The standard risk population was invited, upon informed consent, to undergo the fecal immunochemical test (FIT). Individuals with negative tests were recommended to repeat the FIT after two years, while positives were referred to colonoscopy at the regional center. The medical experts in each screening center, mainly gastroenterology fellows, scheduled the patients for colonoscopy after a prior phone-based evaluation of the risk-benefit balance for the procedure. Cases with decreased life expectancy (Charlson Comorbidity Index ≥6) were referred for standard diagnostic procedures if deemed beneficial [12]. The colonoscopies at the screening center in each region were performed under sedation, by highly experienced endoscopists (licensed in diagnostic and therapeutic endoscopy, undergoing minimum 300 colonoscopies per year and able to manage all the procedures and colonoscopy related adverse events). After the intervention, each patient was provided a detailed report of the procedure and recommendations for follow-up. All the information about the patient (demographics, comorbidities, antithrombotic medication), the procedure (findings, preparation, therapeutic approach, adverse events, sedation), histopathology results were collected in a standardized format in the Electronic Screening Record System according to the EU General Data Protection Regulation [8].

The systematic data collection allowed for a detailed and accurate evaluation of the performance indicators of the program. As of September 2023, a total of 169,052 individuals were offered the FIT across all four regions. The rate of vulnerable individuals was low in Bucharest-Ilfov (19%) and between 57% and 62% in the other regions. The preliminary results reveal a very high rate of FIT acceptance, between 89% and 99%, with a good rate for FIT return ranging from 79 to 95%. The rate of invalid FIT was high in Southwest

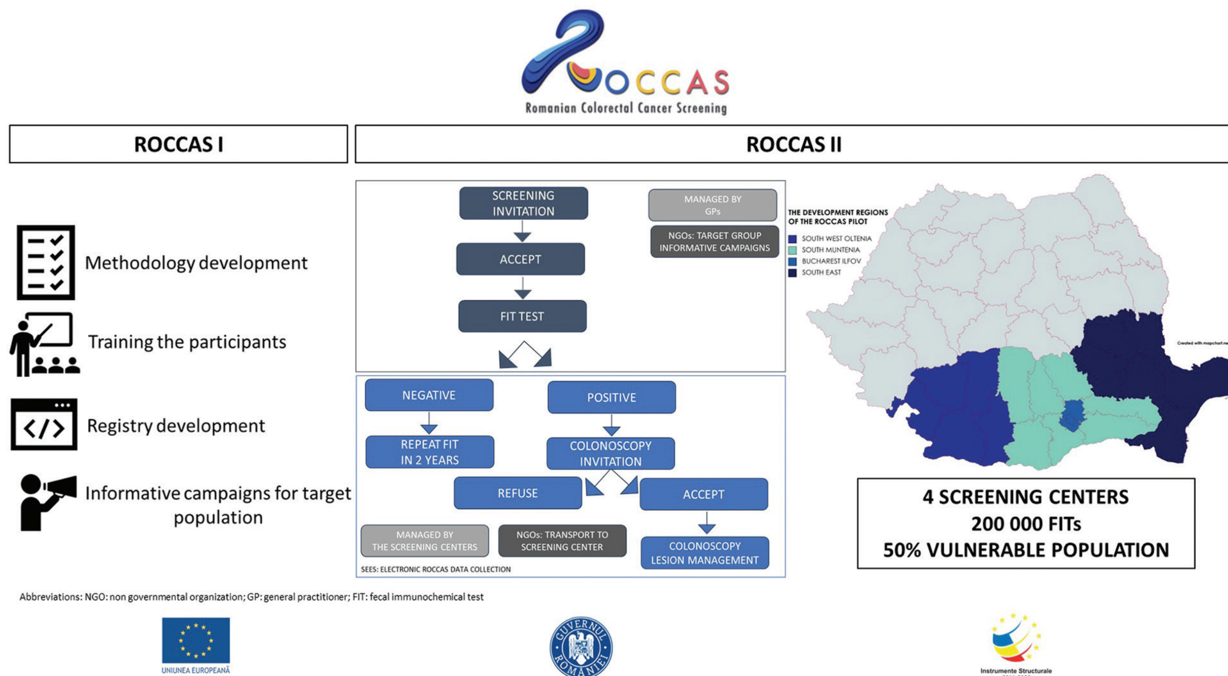

Fig. 1. Timetable of Romanian colorectal cancer screening program.

region (13.2%) and below 3%, in accordance to the EU recommendations in the others [8]. The rate of positive FIT was around 5% in each of the four regions. Between 53% and 55% of the patients underwent colonoscopy subsequent to a positive FIT. The colonoscopy indicators reflected good adherence to the current guidelines' recommendations [10, 11, 13]. The rate of adequate bowel preparation was 84%, withdrawal time 8.65±3.06 minutes, cecal intubation rate 93%, adequate polypectomy technique 82%, polyps were retrieved in 89% of cases, there were no perforations and bleedings were below 2% [14]. The male versus female lesions detection rates were 66% vs. 43% for adenomas and 14% vs. 10% for colorectal cancer.

There are several particularities of the pilot CRC screening program in Romania. The family doctors have an essential role in the recruitment of the target group. The efficacy of this approach in our population is reflected by the high rates of acceptance to the screening invitation. More than half of the screened population included disadvantaged groups. This is in concordance with the objectives of the current National Strategy for Health, Social Inclusion and Poverty Reduction 2015-2020, which stipulates ensuring access to quality health services for vulnerable groups and also the prerogative of equity in screening access of the EU recommendations [8]. The target population included, besides asymptomatic individuals at standard risk for CRC, also patients at increased risk or with symptoms for CRC, who were further referred for diagnostic evaluations, however within the standard national health insurance program. This is especially important to decrease CRC related mortality by diagnosing the disease at early stages. The involvement of gastroenterology fellows in the screening process led to a good case triage that could in part explain the low incidence of adverse events.

The positive results and the experience acquired within the first ROCCAS programs are paving the path for the implementation of the CRC screening at national level. The roll-out to all 8 administrative regions will commence in 2024. Adequate human and financial resources, permanent monitoring and adaptation to the latest EU recommendations will assure the success of the long-term CRC screening continuum in Romania.

Conflicts of interest: None to declare.

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