

REVIEW

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Subject: Competition for the academic position of "ASSOCIATE PROFESSOR", in the scientific specialty "Gastroenterology" at the Gastroenterology Clinic at ASK UMBAL Tokuda EAD, Sofia.

According to Order No. 15-05-258#1/15.12.2025, I was appointed a member of the Scientific Jury, and at the first absentee meeting of the jury I was appointed its chairman, as well as to prepare a review.

One candidate applied for the competition - Dr. Rozalina Ivanova Balabanska, DM, attending physician at the Gastroenterology Clinic at ASK UMBAL Tokuda, EAD, Sofia.

Dr. Rozalina Balabanska was born on 06.11.1963. She graduated from the Higher Medical Institute in Sofia in 1987. She initially worked as a district doctor in the city of Pernik (1987-1991), and subsequently: resident physician at the Gastroenterology Clinic, Military Medical Academy - Sofia (1991-1994); resident physician at the Gastroenterology Department, Fifth City Hospital, Sofia (until 2007); and then until now, attending physician at the Gastroenterology Department at the Gastroenterology Clinic at ASK UMBAL Tokuda. She has acquired specialties in Internal Medicine (1996) and Gastroenterology (1999). She acquired the educational and scientific degree "Doctor" in 2021 and she holds the academic position "Chief Assistant" at the Gastroenterology Clinic at ASK UMBAL Tokuda EAD since 2022. She has been a part-time lecturer at the Faculty of Medicine of Sofia University "St. Kliment Ohridski" since 2020 and leads exercises in propaedeutics of internal medicine and Gastroenterology for 3rd and 4th year medical students. The candidate has conducted training in ultrasound, ultrasound elastography, contrast-enhanced ultrasound, transient elastography, Doppler ultrasound and interventional ultrasound in leading European and national centers, as well as specializations in hepatology and gastrointestinal oncology in prestigious university hospitals in Italy and Spain. She is a principal investigator in pharmaceutical clinical trials I, II, III and IV phases, mainly in the field of hepatology and virology.

The candidate is a recognized national expert in the field of viral hepatitis, hepatic steatosis and a pioneer in transient hepatic elastography, introducing and establishing it for the first time in the country as a leading non-invasive technology for the assessment and staging of hepatic fibrosis and steatosis. He has been a member of the committee for diagnosis and treatment of chronic viral hepatitis at ASK UMBAL Tokuda practically since its inception. Dr. Balabanska is a member of prestigious international organizations such as AASLD, EASL, EFSUMB, WFSUMB.

Dr. Balabanska teaches 3rd and 4th year medical students and supervises gastroenterology residents. The employment record shows that for the period 01.2021- 30.11.2025 the candidate has 1632.5 equiv. hours of teaching workload and during the period she was the supervisor of three gastroenterology residents.

According to the list of publications prepared by her, the candidate participated in the competition with a total of 66 scientific works: one dissertation and 65 publications, of which one monograph, 6 publications related to the topic of the dissertation, 25 publications in refereed journals with an impact factor (of which: 5 full-text publications, reflecting results of multi-center studies; and 20 abstracts from international conferences and congresses), 3 publications in refereed journals without an impact factor and 30 publications in national and non-refereed journals. In addition, a list of participations in scientific forums during the period

1994-2025 is presented, including 48 participations with posters or oral presentations: 21 in Bulgaria and 27 abroad.

The presented citation report from the Central Library of the Medical University of Sofia (No. PT 546/19.11.2025) proves a total of 1271 citations for the period 1995-2025, of which 635 in sources referenced in Scopus, 625 in Web of Science, and 11 in Bulgarian sources from the library fund of the Central Library.

Dr. Balabanska's scientific production is practically in all areas of gastroenterology, but it is most extensive and significant in the field of hepatology where she participated in key clinical trials of therapeutic strategies for chronic viral hepatitis, liver fibrosis associated with hepatic steatosis and steatohepatitis and metabolic dysfunction. Several directions can be outlined:

I. Publications and abstracts from participation in congresses and conferences:

1. Clinical studies of drugs affecting metabolic dysfunction-associated steatohepatitis. Semaglutide is a GLP1 receptor agonist and is a candidate for the treatment of MASH. The candidate participated in a randomized placebo-controlled study, which demonstrated a statistically significant difference with placebo of Semaglutide in the reversal of steatosis and fibrosis, as well as in a significant reduction in body mass index. The study is a phase 3, multicenter, large-scale, including 534 patients in the Semaglutide group and 266 in the placebo group. The results were published in the New England Journal of Medicine. The candidate is also participating in a Phase 2 study of the same drug, investigating the reduction of steatosis and fibrosis at different Semaglutide dose regimens, with the results published in 2021 in the same prestigious publication. The candidate is also participating in another Phase 2 placebo-controlled study of the PAN-PPAR agonist Lanifibranor, which modulates key signaling pathways in the pathogenesis of MASH. The multicenter phase 2 clinical trial demonstrated that the drug improves steatosis and fibrosis and is promising in the treatment of an already common liver disease. The results were published in the New England Journal of Medicine.
2. Randomized placebo-controlled clinical trial of Budenofalk 3x3 mg compared with Budenofalk 9 mg once in patients with active Crohn's Disease (Part of the International Budenofalk Study Group) - the study proves that a single administration of Budenofalk 9 mg is no different in effectiveness and safety with the administration of 3x3 mg and its results have been published in the prestigious Journal of Crohn's and Colitis.
3. Liver elastography: the candidate introduces and validates liver elastography with Fibroscan in the country and participates in the preparation of national recommendations for performing ultrasound liver elastography. The technique, technology, necessary equipment, learning curve and expertise in performing the procedure are defined. Its role is determined as a leading non-invasive test, overcoming some shortcomings of liver biopsy. The recommendations were prepared in co-authorship with nine other national experts and published in the Journal of Diagnostic and Therapeutic Ultrasound. In addition, Dr. Balabanska, in co-authorship with her colleagues from ASK UMHAL Tokuda, presented a large-scale initial experience of over 1000 liver elastographies with Fibroscan at the National Conference on Gastroenterology in 2016. The method is also described in a review article in the GP News Journal.

4. Liver steatosis: the candidate is a leading national expert on the subject. Four publications by Dr. Balabanska in Medical Magazine, GP News and Medinfo (2) explain the problem in detail in accessible language, reveal the risks and methods of diagnosis, as well as possible treatment approaches. Particular attention is paid to the new terminology and modern technological capabilities for non-invasive assessment.
5. Study of the carriage of the mutant allele of IL 28B SNP RS8099917 in the Bulgarian population as a risk factor for progression to chronic hepatitis and cirrhosis in patients with HCV infection: an increased frequency of carriage of this allele is observed among therapy non-responders with hepatitis C. The work is extensive, presented by a multidisciplinary team from several national university hospitals. It has been published as an abstract in the journal Cytokine, the journal Hepatology (supplements), and a supplement of the Journal of Hepatology.
6. New therapeutic strategies in advanced liver fibrosis: the candidate participated in a multicenter Phase 1b/2 study on the use of nanoparticles in advanced liver fibrosis; the results were published as an abstract in the Hepatology journal and presented at a poster session at the AASLD Liver Meeting in Washington, 2017.
7. New therapeutic strategies in chronic hepatitis B: participation in a multicenter non-randomized, "open label" phase 2 study of the effectiveness and safety of linvencorvir (a modulator of the assembly of the capsid of the hepatitis B virus). The study is interesting in design and includes 68 patients: some of whom with suppressed replication by a nucleoside analog, to which linvencorvir is added; others naive, in whom the drug in question is added to therapy with a nucleoside analog with or without pegylated interferon. It is proven that the addition of linvencorvir to therapy is associated with potent inhibition of HBV DNA and RNA, but does not achieve functional cure of the infection. The remaining centers participating in the study are from China, Taiwan, New Zealand, Australia and Singapore and it is published in Clinical and Molecular Hepatology. Also noteworthy is the candidate's participation in a randomized, placebo-controlled Phase 1 study of the safety and tolerability of a TLR 7 agonist (RO7020531). It is known that toll like receptor 7 agonists have potential for the treatment of HBV infection. Participation in a study of such a drug is pioneering in the sense of searching for new therapies for chronic hepatitis B. Both healthy volunteers and patients with HBV infection were included. The studied drug demonstrated a promising safety profile, the data were published in the Lancet Infectious Diseases journal, with the candidate as second author.
8. Participation in clinical trials of other new drugs for Hepatitis B: vebicorvir (cor inhibitor first generation); R07049389 (allosteric modulator of the cor protein). Abstracts are presented from poster presentations published in the Journal of Hepatology. Also, Phase 1 study with a TLR 7 agonist in patients with chronic hepatitis B without antiviral therapy: co-authorship of a poster at the AASLD Liver Meeting.
9. Co-authorship of an analysis of predictors of HBeAg loss in patients with Hepatitis B on therapy with tenofovir alafenamide or tenofovir disoproxil fumarate: the data

are presented as an abstract published in HIV Medicine (Suppl), a supplement to Hepatology.

10. Presentation of results of long-term cyclic treatment with PegIFN alpha-2a in patients with chronic hepatitis B. Reduction of HBsAg in HBeAg negative patients with genotype D is established within the framework of a national multicenter study, the results of which are presented as an abstract in the Journal of Hepatology.
11. Participation in a national non-randomized study for the treatment of HBeAg negative Chronic hepatitis B with pegylated interferon alpha 2a.
12. Study of depression in patients with hepatitis C on treatment with pegylated interferon: participation in a multicenter study, and the abstract is published in the Journal of Hepatology.
13. Study of the early virological response and flu-like symptoms when administering controlled-release interferon in patients with Hepatitis C in combination with Ribavirin (also multicenter studies).
14. Proof of the lack of correlation between ALT levels and histological activity in patients with hepatitis C: original study led by Academician Grigor Mechkov: abstracts in "World Congresses of Gastroenterology" (Wien 1998), and in the Journal of Hepatology (2000).
15. Frequency of mixed cryoglobulinemia in patients with hepatitis C: own data under the leadership of Academician Grigor Mechkov, presented at UEGW Birmingham in 1997, published the same year in "Modern Medicine" as well.
16. Studies of various interferon-based strategies in patients with hepatitis C, including "special" groups, such as those treated with Methadone and Revia.
17. In a study conducted jointly with the Hemodialysis Clinic of ASK UMBAL Tokuda, the frequency of HCV infection among patients with CKD on dialysis was analyzed for a three-year period, as well as the possibility of implementing the recommendations of "Kidney Disease: Improving Global Outcomes" (KDIGO) and adapting them to Bulgarian conditions; the possible mechanisms of infection and treatment strategies in this specific high-risk population were also analyzed.
18. Focal lesions in the spleen: own observation on over 14,000 patients, in whom abdominal ultrasound was performed and in 56 of them focal changes in the spleen were found (from calcifications to infiltration by lymphoproliferative process, echinococcosis and metastases). Important conclusions were made regarding the frequency of focal processes in the spleen and the need for precise ultrasound examination especially in the context of certain clinical conditions. The data were published in 1998.
19. Publications of interesting and rare clinical cases in national periodicals with a practical focus as follows: multiorgan damage after use of anabolic steroids; Alpha-1 antitrypsin deficiency; Dubin-Johnson syndrome; liver involvement in

infectious mononucleosis; hereditary transthyretin amyloidosis; giant fibrovascular esophageal polyp, Gardner's syndrome; worsening of psoriasis during interferon therapy for Hepatitis B.

20. Magazines "Healthy Shop" and "Hello! Stay Healthy!" - explanations in accessible language on the topic of viral hepatitis, colorectal cancer, damage to the gastrointestinal tract from non-steroidal anti-inflammatory drugs, the harm of smoking, indications for the use of Hidrasec, presentation of interesting clinical cases, etc.

II. Monograph

The candidate presents a monograph entitled "Liver Steatosis". The work is impressive in its scale, modernity and comprehensiveness. The book is the first in the country to treat a very current problem: liver steatosis. The author defines the problem and its significance. Steatosis is the most frequently diagnosed pathological liver finding with increasing importance in modern society. Increased calorie intake, hypokinesia, as well as the ever-present consumption of alcohol are among the main reasons for the widespread spread of steatosis. It is emphasized that 25-30% of the world's population has steatosis, it is found in 70% of overweight patients, 90% of those with obesity and 70% of diabetics. It is not by chance that there are comments about a global pandemic of obesity and hepatic steatosis. Its two main forms are examined in details: one which is related to metabolic dysfunction, and the other associated with increased alcohol consumption. The most modern definition, histological forms, historical facts, new terminology, natural course and evolution, treatment strategies are presented. The key role of insulin resistance, and the close relationship with diabetes and obesity are described. Genetic factors, new concepts about the role of adiponectin, sex hormones, ovarian polycystic disease and the importance of the intestinal microbiome are also examined. The pathobiochemical mechanisms, the importance of fat accumulation in liver cells and possible evolution are described in great detail and illustrated with explanatory schemes. Diagnostic tests, including imaging diagnostics, are reviewed, and the advantages and disadvantages of the different methods are highlighted. A clinical behavior algorithm is proposed. The multicomponent nature of treatment is emphasized, focusing mainly on lifestyle changes, reducing calorie intake and increasing physical activity. Drug therapy is discussed in detail, including the use of new drugs and their potential future role in the therapeutic algorithm, as well as the aggressive treatment of concomitant diseases such as diabetes mellitus, arterial hypertension, dyslipidemia, etc. It is emphasized that steatosis is completely reversible if the causes of its occurrence are identified and eliminated in time. This, in turn, emphasizes the need for timely diagnosis with non-invasive tests and rapid action to control it. The need for a complex multidisciplinary approach to these patients is emphasized; a logical clinical algorithm is proposed in patients with metabolic syndrome as well as action sequence to clarify unclear liver disease. The monograph reflects the most modern aspects of hepatic steatosis: from the risk factors for its occurrence, through precise diagnostics and treatment strategies to possible unfavorable evolution into liver cirrhosis and primary liver cancer. The undeniable merits of this book make it a valuable reading, not only for gastroenterologists, but also for specializing doctors, students, as well as colleagues from other specialties (endocrinologists, cardiologists, etc.).

III. Dissertation

The candidate presents a dissertation on the topic "Liver steatosis and non-alcoholic steatohepatitis: clinical assessment and application of transient elastography (Fibroscan)"

The work is large-scale and represents a retrospective observational study, including 170 patients with metabolic syndrome and metabolic dysfunction-associated steatotic liver disease in different stages (from simple steatosis through steatohepatitis and fibrosis to early cirrhosis). The patients were evaluated in extreme details, and in 135 of them a liver biopsy was performed with assessment of inflammatory activity and fibrosis using different scoring systems. In 20, a liver "Multiscan" was performed, including magnetic resonance spectroscopy with quantitative determination of fat and iron and calculation of LIF score. All of them underwent a Fibroscan study to assess fibrosis and steatosis. A positive relationship between body weight, BMI, waist circumference and fat accumulation in the liver was proven. The role of Fibroscan as a highly informative non-invasive method for assessing both fibrosis and steatosis was confirmed, with the author introducing his own "cut-off" values for staging steatosis by measuring CAP with Fibroscan. The algorithm proposed by the author for assessing the condition of the liver in patients with metabolic syndrome or type 2 diabetes mellitus is particularly original and applicable in daily clinical practice, including certain anamnestic data, anthropometric parameters, a package of laboratory tests, ultrasound, transient elastography with Fibroscan and quantitative assessment of CAP for the degree of steatosis, as well as calculation of FIB 4 and FAST Score for differentiating patients with advanced fibrosis and risk of progression. The work reinforces the role of non-invasive tests for the assessment of steatosis and introduces into clinical practice and establishes in the country the Fibroscan study for measuring steatosis and determining stiffness (fibrosis) as an indispensable part of the assessment of every liver patient, with a particularly important role in patients with diabetes and obesity.

Contributions of the dissertation:

1. Creation of own cut-off values for staging of liver steatosis based on measurement with CAP on Fibroscan.
2. Creation of own cut-off values for staging of liver fibrosis based on measurement with transient elastography with Fibroscan device.
3. Creation of an algorithm for behavior in patients with a "liver problem": changes in liver laboratory tests or ultrasound findings. The algorithm is easily applicable in daily clinical practice.
4. Creation of an algorithm for examining the condition of the liver in any patient with obesity, diabetes mellitus or metabolic syndrome, also adapted.

The creative achievements and scientific and applied contributions of the candidate are of unquestionable great importance for the development of gastroenterology and hepatology in the country. Several directions are distinguished:

1. Introduction in the country and approval of liver elastography with Fibroscan. Participation in the preparation of national recommendations for liver elastography.
2. Liver steatosis: creation of a large-scale literary work, which is the first and only of its kind in the country and summarizes the most up-to-date data on the nature and clinical significance of liver steatosis, its etiopathogenesis, diagnostics and treatment strategies. The published monograph on this topic is a particularly valuable reading, both for Bulgarian gastroenterologists, as well as for residents, medical students, and for doctors from other specialties (cardiologists, endocrinologists and surgeons). The topic is presented in an accessible language and in several national publications.
3. In-depth research in the field of chronic viral hepatitis: a significant contribution to the introduction of new therapeutic regimens in the country.

4. Participation in clinical trials of new treatment strategies for Chronic Hepatitis B, C, associated with metabolic dysfunction associated steatohepatitis, liver fibrosis, Crohn's Disease: gaining valuable experience with medications that are about to enter clinical practice, as well as their dosage regimens; especially valuable are the accumulated data on linvencorvir, the TLR7 agonist RG 7854, Semaglutide and its dosage regimens, the dosage of Budenofalk 9 mg once daily in Crohn's Disease.

5. Publication of interesting and rare clinical cases with a contribution to the differential diagnostic process and enrichment of the knowledge of Bulgarian clinicians about rare conditions in medicine.

6. Proclamation of a healthy lifestyle with avoidance of smoking and obesity. Informing the public about the potential harm of steatosis and viral hepatitis.

Considering the serious theoretical and practical training of Dr. Rozalina Balabanska, her teaching activities, scientific publications, her research activities, her participation in prestigious national and international scientific forums, her vast experience as a clinician-gastroenterologist and hepatologist, fully covering and even exceeding the requirements set forth in the ZRASRB and the Regulations for the Development of the Academic Staff of the National Board at ASK UMHAL Tokuda EAD, I recommend to the esteemed members of the Scientific Jury to give **a positive vote and elect Dr. Rozalina Ivanova Balabanska, MD as ASSOCIATE PROFESSOR at the Clinic of Gastroenterology at ASK UMHAL Tokuda EAD.** I have the honor of knowing the candidate personally and working with her for 14 years now and I am fully convinced of her professional qualities, ethics, high morals, as well as her potential for academic growth.

02.01.2026
Sofia

With respect:
/Prof. P. Karagyozev, D.M., FASGE/

