Proper Medical Writing

PROPER MEDICAL WRITING

Professional Medical Communication | Strategic Publication Planning | Translations | Medical Writing | Editing | Proofreading
Regulatory Writing | Statistics | Training | Patient Registries | Observational Studies | Patient - reported Outcomes

www.propermedicalwriting.com

Proper Medical Writing

ABOUT US

We are a dynamically developing medical writing agency, with a firm position in the Central European market.
We specialise in:

- preparing and editing scientific texts, particularly medical publications
- devising publication strategies
- translating specialist medical and scientific texts
- designing and documenting clinical trials, according to current guidelines
- designing and running observational studies and patient registries
- preparing formal documentation for drug safety and registration
- processing medical and scientific information: professional evaluations; expert meetings, including investigator meetings and advisory board meetings
- organising specialised training in the fields of: medical writing (including drug regulatory and academic writing), statistics in clinical studies and public speaking
- translating and validating patient-reported outcome (PRO) forms, including quality of life (QoL) questionnaires, according to current guidelines

As a company, we pride ourselves in a high intellectual capital and links to multiple experts from Europe, Australia and the United States. Our knowledge of the medical field has inspired trust in many pharmaceutical companies, institutes and scientific societies.

PREPARATION OF SCIENTIFIC PAPERS

We provide professional support at all stages of scientific data processing and academic writing for publication in leading journals, including:

- original research papers
- review articles
- commentaries
- letters to the editor
- case reports
- meta-analyses
- academic assessment of sources (e.g. final investigation report)
- statistical consultations
- native speaker proofreading
- literature reviews and bibliography validation
- analysis of the potential to publish
- journal selection based on academic content and expected impact factor
- preparation of covering letters to journal editors
- editing and formatting according to IMRAD[1]/ICMJE[2] requirements and journal guidelines
- preparing responses to reviewers' remarks

Assistance in preparation of a scientific paper involves close co-operation between the author and an expert medical writer, and encompasses preparation of all sections of an article including:

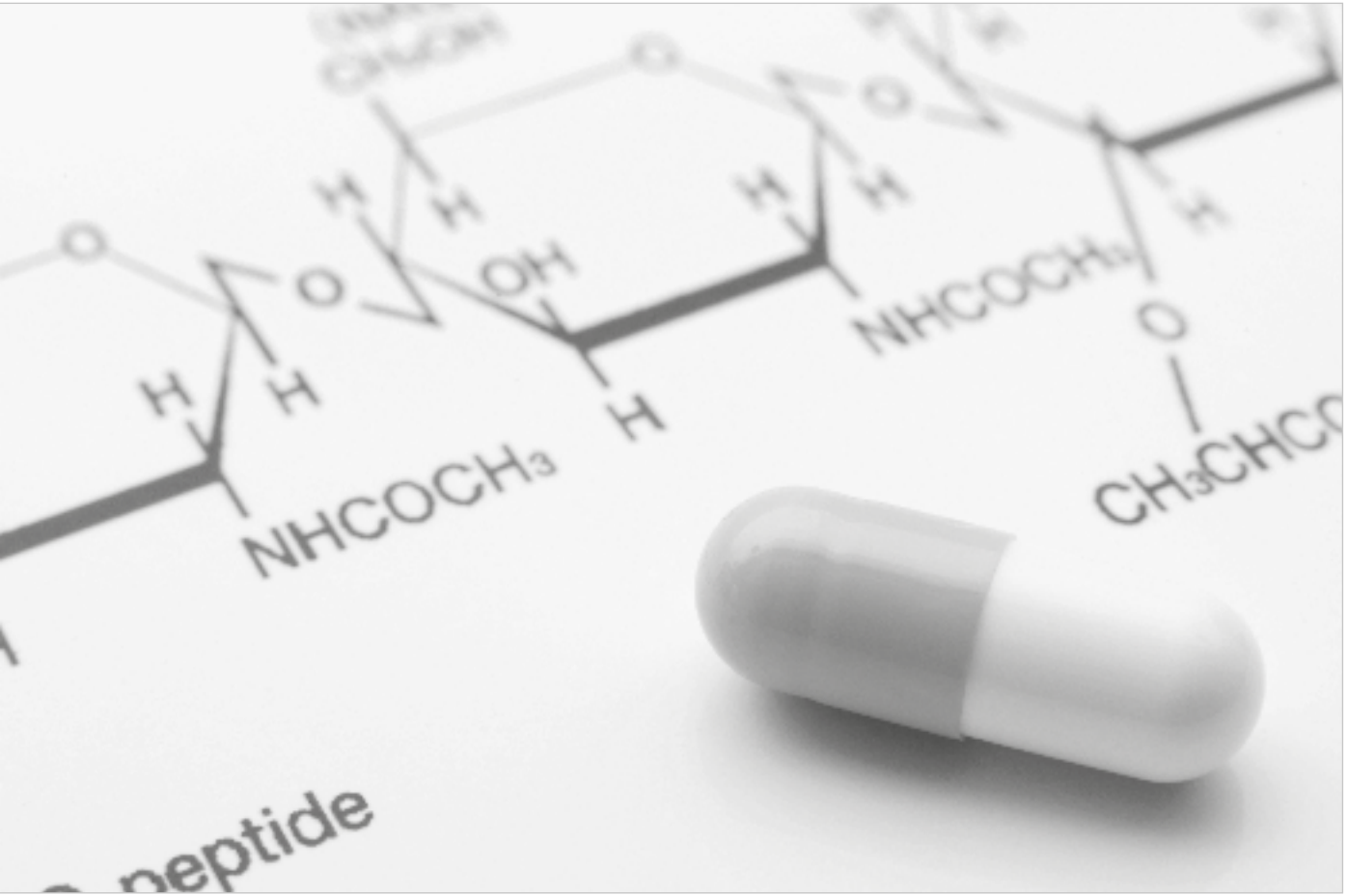
- appropriate planning of the article
- preparation of the abstract, introduction and methods sections
- selection and presentation of results
- suggestions for the discussion
- selection of corresponding references

We carefully follow the GPP3[3] guidelines, developing articles and presentations in a responsible and ethical manner – Good Publication Practice for communicating company sponsored medical research[4].

[1]IMRAD: The structure of scientific papers, which are divided into the following sections: Introduction, Methods, Results, and Discussion
[2]ICMJE: International Committee of Medical Journal Editors
[3]GPP: Good Publication Practice
[4]Battisti W, Wager E, Baltzer L, et al. Good Publication Practice for Communicating Company-Sponsored Medical Research: GPP3. Ann Intern Med. 2015;163:461-464. doi:10.7326/M15-0288.

MEDICAL TRANSLATION

We offer the translation of any medical or regulatory text into English, and from English into Polish. We use existing dictionaries of preferred terminology or can devise customised dictionaries.



The process of translation encompasses:

- analysis of the source text for:
  - appropriateness of style and vocabulary, logical structure, and coherence
  - factual errors or inaccuracies
- translation by a translator in co-operation with a relevant specialist
- error correction and proofreading by a native speaker with appropriate knowledge

PATIENT-REPORTED OUTCOMES AND PATIENT FEEDBACK QUESTIONNAIRES

We translate and validate patient-reported outcome (PRO) forms, including quality of life (QoL) questionnaires, from English into Polish. The Polish versions of QoL questionnaires are prepared using double translation (forward and backward), according to the guidelines of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR)[5]. Alternatively, we use dual translation panels[6].

We also create original PRO forms, and offer validation of newly devised ones.

We provide patient feedback questionnaires for:

- quality of life
- treatment and health care satisfaction
- symptom and complaint assessment
- personal, professional, and social functioning
- general health

The PRO forms we prepare may be used (also electronically) in multicentre clinical trials (with centres using different operational languages), observational studies, patient registries, and day-to-day medical practice.

At the same time, we can provide advice on the selection of an appropriate questionnaire for a planned clinical study, or supervise the process of creating a new form.

[5] Principles of Good Practice for the Translation and Cultural Adaptation Process for Patient-Reported Outcomes (PRO) Measures: Report of the ISPOR Task Force for Translation and Cultural Adaptation, Value in Health, 2005;8(2):95-104
[6] Swaine-Verdier A, Doward LC, Hagell P, et al. Adapting quality of life instruments, Value in Health, 2004;7(suppl. 1):s27–s30

DESIGN AND MAINTENANCE OF PATIENT REGISTRIES AND OBSERVATIONAL STUDIES

We provide simple solutions for the maintenance of complex patient registries, conducting observational studies, post-marketing studies (PMS) and post-authorisation safety studies (PASS) according to the Good Clinical Practice (ICH-GCP[7]) guidelines, the requirements of the European Medicines Agency (EMA) and standard operating procedures (SOPs). Moreover, the interactive solutions we offer enable close co-operation between investigators and sponsors, and they facilitate the day-to-day clinical care of the patient (patient management tools).

DOCUMENTATION OF CLINICAL STUDIES

The documentation of clinical studies submitted to regulatory agencies in Poland (URPL, The Office for Registration of Medicinal Products), and elsewhere (EMA, Food and Drug Administration [FDA]), and to bioethics committees, includes the following:

- study protocol
- investigator brochure
- standard operating procedure
- electronic case report form
- patient informed consent form
- narratives
- statistical analysis plan
- statistical report
- periodic safety update report
- development safety update report
- interim analysis report
- clinical study report

STATISTICAL ANALYSES

As part of our complex clinical trial service, we offer statistical analyses including:

- calculation of sample size and test power
- descriptive statistics
- qualitative and quantitative analyses
- advanced statistical methods
- interpretation of results

[7]ICH - GCP: International Conference on Harmonisation – Guideline for Good Clinical Practice

MEDICAL COMMUNICATION AND E-MARKETING FOR PHARMACEUTICAL INDUSTRY

We prepare up to date medical information for diseases, therapies and medicinal products. In addition, we create, translate, and proofread administrative and internal medical communications, including those for strategic meetings, and those with opinion-forming subjects:

- manuscripts
- conference reports
- monographs
- commentaries
- presentations
- posters
- patient information
- content for medical (including product-specific) websites

We also do:

- medical database searches
- medical writing for the internet
- administration of health-related websites (production and managing of the content, search engine optimisation, usability optimisation)

ADVISORY BOARDS, PROFESSIONAL EVALUATIONS AND EXPERT MEETINGS

Organisation and full operational support including scientific report preparation of:

- advisory boards
- panel discussions
- individual discussions with experts in the relevant field
- discussion panels based on prepared literature reviews
- investigator meetings
- Delphi panels (anonymous questioning of experts in order to predict the long-term trends in scientific research and development)

The above services can be provided with direct input from the commissioning party or exclusively by representatives of Proper Medical Writing.

The expert meeting preparation service includes the following stages:

- problem definition and precise identification of the subject range, as well as the specific questions and issues to be addressed
- identification of experts, preparation of a proposed list of experts, and deciding on the final choice of experts working with the client
- identification of information sources
- selection of the most efficient means of information acquisition (e.g. advisory board, panel discussion)
- logistics and content-related preparation for an advisory board or panel discussion
- summary, analysis and synthesis of the acquired information
- preparation of a report or minutes
- preparation of a publication

TRAINING

Since 2007, Proper Medical Writing has organised workshops and conferences, during which over 1000 people have been trained, both in Poland and elsewhere. We organise tailored training events, adjusted to the ability of the participants, as well as open sessions aimed at physicians, scientists, investigators and pharmaceutical companies (marketing, medical, clinical, drug registration and safety departments). Our training is performed in an objective manner and characterised by high-quality content.

Training is an effective means to broadening your range of key knowledge and skills, and serves to support the scientific developments pertaining to clinical trials, including PMS. Our lecturers are authors of multiple publications and specialists with extensive experience in scientific presentation at multinational conferences, symposia, and other meetings, as well as in academic writing, the art of presenting and preparation of formal medical documentation.

We currently offer courses on:

- presenting medical data at scientific meetings
- medical writing (how to write a scientific paper)
- clinical trial documentation
- scientific publishing
- clinical statistics for non-statisticians (how to read and understand statistics)
- oral presentation skills
- research grants
- critical appraisal of published papers
- critical appraisal of study proposals
- clinical study design, statistics & PROs
- medical writing and communication for medical affairs
- evidence-based medicine
- medical databases

Examples of Past International Courses:

- Writing a Scientific Publication, 16th European Congress of Endocrinology, 3 May 2014, Wrocław, Poland
- Clinical Study Design, Statistics & Patient-Reported Outcomes (PROs), 28–29 January 2014, Dubai, United Emirates
- Medical Writing, 15th European Congress of Endocrinology, 27 April 2013, Copenhagen, Denmark
- Medical Writing, Statistics, Oral Presentation Skills and Poster Session Course, 31 January–2 February 2013, Prague, Czech Republic
- Medical Writing, 15th International Congress of Endocrinology and 14th European Congress of Endocrinology (ICE/ECE 2012), 5 May 2012, Florence, Italy
- Medical Writing and Statistics Course, 9–10 March 2012, Budapest, Hungary
- Presenting Medical Data & Medical Writing Course, 9-10 April 2010, Belgrade, Serbia

PROPER MEDICAL WRITING ADHERES TO THE FOLLOWING GUIDELINES AND DIRECTIVES:

- Unified principles of Good Clinical Practice (the ICH-GCP guidelines), or their local legal equivalents
- European Parliament Directive 2001/20/EC regarding medicinal products used in humans
- European Parliament and Council Directive 2005/28/EC regarding the principles and detailed guidelines for GCP, including updates
- Uniform Requirements for Manuscripts Submitted to Biomedical Journals, devised by the International Committee of Medical Journal Editors (ICMJE)
- Good Publishing Practice for companies sponsoring medical research (GPP3 guidelines)
- All domestic and local regulations, principles and guidelines important for the delivery of services, including any rules and regulations announced by an appropriate regulatory body, as well as any other accepted standards

ABOUT PROPER MEDICAL WRITING (PMW)

The company was founded in 2003, as a part of the infrared group, and since the start of its operations focused on providing interdisciplinary scientific/technical/marketing solutions for the pharmaceutical industry. In 2007, it entered the field of scientific result presentation and publishing. As a consequence of a steady growth, PMW started to operate independently in 2014. More than 10 years of experience has resulted in many permanent contracts and the position of preferred supplier to many pharmaceutical companies.

Our team

The PMW team consists of experienced professionals from various medical and bioscience-related backgrounds. Many of them have higher degrees (MD or PhD), and graduated in more than one life sciences field. Thanks to a broad portfolio of specialists, we can ensure the appropriate selection of expert teams, which lead by a project manager guarantees optimum results.

We have been trusted by:

Pharmaceutical and biotechnological companies:
2KMM, Abbott Laboratories, Adamed, Amgen, AOP Orphan, AstraZeneca Pharma, Bayer, Bioton, Boehringer Ingelheim, Bristol-Myers Squibb, Celon, Chiesi, Pharma, Danone, Egis, Eli Lilly, Eusa Pharma, GlaxoSmithKline, ICON, Ipsen, Janssen-Cilag, Medicus, MSD, Mundipharma, Novartis, Novo Nordisk, Nycomed (Takeda), Pfizer, Phytopharm, Polski Lek, Russlan Clinical Research, Roche, Sanofi, UCB Pharma, Woerwag

Teaching hospitals, medical and scientific institutions:
Agency for Health Technology Assessment in Poland, Institute of Biotechnology and Antibiotics, Institute of Cardiology in Warsaw, Institute of Mother and Child, John Paul II Specialist Hospital in Cracow, Medical University of Gdansk, Medical University of Warsaw, National Institute of Hygiene, Non-Public Health Care Provider 'Nasz Lekarz (Our Doctor)' in Torun, Polish Mother's Memorial Hospital, Poznan University of Medical Sciences, Royal Dent, The Foot Clinic in Warsaw, Wroclaw Medical University

We collaborate with medical societies:

European Society of Endocrinology, Polish Cardiac Society, Polish Dermatological Society, Polish Society of Oncology, Polish Ophthalmological Society, Polish Society for Rheumatology, Polish Transplantation Society

Selected publications supported by Proper Medical Writing – ordered by index factor (IF):

• Flisiak R, Janczewska E, Wawrzynowicz-Syczewska M. Real-world effectiveness and safety of ombitasvir/paritaprevir/ritonavir ± dasabuvir ± ribavirin in hepatitis C: AMBER study. AP&T 2016; DOI 10.1111/apt.13790 **[IF 6.32]**

• Jurecka-Lubieniecka B, Ploski R, Kula D, Krol A, Bednarczuk T, Kolosza Z, Tukiendorf A, Szpak-Ulczok S, Stanjek-Cichoracka A, Polanska J, Jarzab B. Association between age at diagnosis of Graves' disease and variants in genes involved in immune response. PLoS One. 2013;8(3):e59349. doi: 10.1371/journal.pone.0059349. Epub 2013 Mar 27 **[IF 4.090]**

• Moll JJ, Michalak KW, Młudzik K, Moszura T, Kopala M, Moll M, Moll JA. Long-term outcome of direct neopulmonary artery reconstruction during the arterial switch procedure. Ann Thorac Surg. 2012 Jan;93(1):177-84. Epub 2011 Nov 23 **[IF 3.631]**

• Koltowski L, Koltowska-Haggstrom M, Filipiak KJ, Kochman J, Golicki D, Pietrasik A, Huczek Z, Balsam P, Scibisz A, Opolski G l. Quality of life in patients with ST-segment elevation myocardial infarction undergoing percutaneous coronary intervention - radial versus femoral access (from the OCEAN RACE Trial). Am J Cardiol. 2014 Aug 15;114(4):516-21. doi: 10.1016/j.amjcard.2014.05.030. Epub 2014 Jun **[IF 3.425]**

• Siegel S, Milian M, Kleist B, et al. Coping strategies have a strong impact on quality of life, depression, and embitterment in patients with Cushing's disease. Pituistary 2016; 19(5) DOI 10.1007/s11102-016-0750-. **[IF 3.407]**

• Wikiera B, Mulak M, Kołtowska-Haggstrom M, et al. The presence of eye defects in patients with Turner syndrome is irrespective of their karyotype. Clin Endocrinol DOI: 10.1111/cen.12794. **[IF 3.353]**

• Hojan K, Molińska-Glura M, Milecki P. Physical activity and body composition, body physique, and quality of life in premenopausal breast cancer patients during endocrine therapy - a feasibility study. Acta Oncol. 2013 Feb;52(2):319-26. doi: 10.3109/0284186X.2012.744468. Epub 2012 Nov 29. **[IF 3.330]**

• Wolnik B, Hak L. Multicenter, open-label, non-randomized, non-interventional observational study of safety of treatment initiation with a biphasic insulin aspart. Expert Opin Drug Saf. 2013 Mar;12(2):137-44. doi: 10.1517/14740338.2013.761971. Epub 2013 Jan 7. **[IF 3.015]**

• Mikuła T, Cianciara J, Wiercińska-Drapało A. Is there any influence of immune deficit on procalcitonin results? Hum Immunol 2011 Dec;72(12):1194-7. Epub 2011 Aug 30 **[IF 2.872]**

• Koch A, Jozwiak M, Idzior M, et al. Avascular necrosis as a complication of the treatment of dislocation of the hip in children with cerebral palsy. Bone Joint J 2015;97-B:270–6. **[IF 2.801]**

• Jassem J, Ozmen V , Bacanu F, et al. Delays in diagnosis and treatment of breast cancer: a multinational analysis. DOI: http://dx.doi.org/10.1093/eurpub/ckt131 **[IF 2.459]**

• Jahnz-Różyk K, Szepiel P. Early impact of treatment with tiotropium, long-acting anticholinergic preparation, in patients with COPD – real-life experience from an observational study. Int J Chron Obstruct Pulmon Dis. 2015;10:613-23. **[IF 2.732]**

• Bodzenta-Łukaszyk A, Kokot M. Pharmacological consequences of inhaled drug delivery to small airways in the treatment of asthma. Adv Ther. 2014 Aug;31(8):803-16. doi: 10.1007/s12325-014-0143-7. Epub 2014 Aug 13. **[IF 2.438]**

• Drzał-Grabiec J, Snela S, Rykała J, Podgórska J, Banaś A. Changes in the body posture of women occurring with age. BMC Geriatrics 2013, 13:108 doi:10.1186/1471-2318-13-108. **[IF 2.340]**

• Szajewski M, Kruszewski WJ, Lakomy J, Ciesielski M, Kawecki K, Jankun J, Buczek T, Szefel J. VEGF-C and VEGF-D overexpression is more common in left-sided and well-differentiated colon adenocarcinoma. Oncol Rep. 2014 Jan;31(1):125-30. doi: 10.3892/or.2013.2821. Epub 2013 Oct 25. **[IF 2.297]**

• Marek-Trzonkowska N, Myśliwec M, Siebert J, Trzonkowski P. Clinical application of regulatory T cells in type 1 diabetes. Pediatr Diabetes. 2013 Aug;14(5):322-32. doi: 10.1111/pedi.12029. Epub 2013 Apr 30. **[IF 2.160]**

• Jurczak W, Kroll-Balcerzak R, Giebel S, Machaczka M, Giza A, Ogórka T, Fornagiel S, Rybka J, Wróbel T, Kumiega B, Skotnicki AB, Komarnicki M. Liposomal cytarabine in the prophylaxis and treatment of CNS lymphoma: toxicity analysis in a retrospective case series study conducted at Polish Lymphoma Research Group Centers. Med Oncol. 2015;32:520. **[IF 2.058]**

• Drzał-Grabiec J, Snela S. Effect of high-heeled shoes on the parameters of body posture. Spine (Phila Pa 1976). 2013 Sep 15;38(20):1785-9. **[IF 2.159]**

• Drużbicki M, Rusek W, Snela S, Dudek J, Szczepanik M, Zak E, Durmala J, Czernuszenko A, Bonikowski M, Sobota G. Functional effects of robotic-assisted locomotor treadmill therapy in children with cerebral palsy. J Rehabil Med. 2013 Apr;45(4):358-63. doi: 10.2340/16501977-1114. **[IF 2.049]**

• Jurczak W, Kroll-Balcerzak R, Giebel S, et al. Liposomal cytarabine in the prophylaxis and treatment of CNS lymphoma: toxicity analysis in a retrospective case series study conducted at Polish Lymphoma Research Group Centers. Med Oncol. 2015; 32(4):90 **[IF 2.058]**

• Gil L, Kazmierczak M, Kroll-Balcerzak R, et al. Bendamustine-based therapy as first-line treatment for non-Hodgkin lymphoma. Med Oncol. 2014; 31(5): 944 **[IF 2.058]**

• Jackowska T, Pluta J. Routine infant immunization with the 7- and 13-valent pneumococcal conjugate vaccines: current perspective on reduced-dosage regimens. Arch Med Sci. 2012 Jul 4;8(3):542-8. doi: 10.5114/aoms.2012.29410 **[IF 1.890]**

• Jamry A, Jałyński M, Piskorz L, et al. Assessment of adhesion formation after laparoscopic intraperitoneal implantation of Dynamesh IPOM mesh. Arch Med Sci 2013; 9, 3: 487-492 **[IF 1.890]**

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• Drzał-Grabiec J, Snela S, Rachwał M, Rykała J, Podgórska J. Effects of carrying a backpack in a symmetrical manner on the shape of the feet. Ergonomics. 2013;56(10):1577-83. doi: 10.1080/00140139.2013.828102. Epub 2013 Sep 10. **[IF 1.674]**

• Pychyńska-Pokorska M, Pągowska-Klimek I, Krajewski W, Moll JJ. Use of recombinant activated factor VII for controlling refractory postoperative bleeding in children undergoing cardiac surgery with cardiopulmonary bypass. J Cardiothorac Vasc Anesth. 2011 Dec;25(6):987-94. doi: 10.1053/j.jvca.2011.05.012. Epub 2011 Aug 11 **[IF 1.596]**

• Szmit S, Jank M, Maciejewski H, Grabowski M, Glowczynska R, Majewska A, Filipiak KJ, Motyl T, Opolski G. Gene expression profiling in peripheral blood nuclear cells in patients with refractory ischaemic end-stage heart failure. J Appl Genet. 2010;51(3):353-68. Journal of Applied Genetics **[IF 1.482]**

• Luterek K, Szymusik I, Bartkowiak R, Koltowski L, Filipiak KJ, Wielgos M. N-terminal pro-B-type natriuretic peptide: a potential marker of fetal heart failure in hemolytic disease. Neuro Endocrinol Lett. 2011;32(5):657-62. **[IF 1.296]**

• Tomasz Jaxa-Chamiec. Vitamins and myocardial infarction in diabetics, In: Watson R, editor. Cardiovascular disease. Academic Press; 2012

• Jarosław Wasilewski, Lech Poloński. An introduction to ECG interpretation. In: ECG signal processing, classification and interpretation. London: Springer; 2012

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