comprehensive data on the efficacy and safety of such products, is retained. In addition, opinions for cohort compassionate use of products eligible to the centralised procedure may be given by the EMEA to treat patients with chronically or seriously debilitating disease, considered life-threatening, when no other authorised alternative exists.
The new European pharmaceutical legislation contains a number of new tools to provide early access to medicinal products of public health interest. The new approval mechanisms and the impact on the authorisation of oncology drugs are reviewed based on EMEA guidance.
Disclaimer: The views presented in this abstract are those of the authors and should not be understood or quoted as being made on behalf of the EMEA or its scientific committees

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Conduct of international multi-centre Investigator-Initiated Trials (IIT) in Europe after the transposition of the Clinical Trials Directive in national Member States law

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Background: Due to the mandatory implementation of the Clinical Trials Directive, Member States (MS) of the European Union (EU) have adapted their existing legislation to the new requirements for the conduct of clinical trials into humans. The Directive is aimed to harmonise legal acts for the set-up, conduct and reporting of clinical trials, to implement GCP-principles European-wide and to enforce patient protection. For non-commercial trials, the Directive is seen to impede the realization of future trials, as requirements, obligations and costs for clinical research projects are considerably increasing.
Methods: The comparative analysis carried out is aimed to investigate differences, obstacles and pitfalls for the conduct of future multi-centre trials in MS. The legislation of 8 MS has been revised, major differences and alleviations allowed for non-commercial trials are tabulated. 3 IIT case studies in oncology are presented; the feasibility to conduct each trial throughout the EU will be discussed.
Results: Major differences are noticed regarding the scope of revised legislations in the MS. Differences also apply to sponsorship and liability issues. Until now, only a few MS have expressively added provisions for non-commercial trials into their legislation. These specify e.g. the use of commercially available products and address reimbursement issues, simplified or exempted submissions of an Investigational Medicinal Product Dossier to competent authorities, or allow for exemptions from fees for IRB/dossier approval. No common definitions are available throughout the EU neither for the so-called 'Phase IV' studies, nor for the terms 'IIT' or 'non-interventional studies'.
Conclusion: The new legal framework for clinical trials renders the realization especially of future pan-European multi-centre trials much more difficult. In having harmonised organisational requirements for trials throughout the EU, the Directive has failed to simplify the conduct of academic clinical trials in the European trial space. Radiotherapy studies, trials investigating surgical techniques and some multi-modal trial concepts remain in some, but not all MS out of the scope of the revised legislative texts. Apart from 'interventional' trials, non-interventional trials allow – although heavily restricted to small Phase I/II case series within or in close proximity to the approved prescription window given by drug labelling – in some MS limited research in form of observational studies outside of the new legal framework. 12 months after implementation, the new EU legislation results in a harsh drop-down of the number of new clinical trials and promotes primarily the conduct of nation-wide research projects.

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Study participation improves treatment strategies and individual patient care in participating centers

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The ADEBAR study is a prospective multicenter Phase III trial to examine whether high-risk breast cancer patients (> 4 involved axillary lymph nodes) benefit from a sequential anthracycline-docetaxel regimen (E90C-D: 4 cycles epirubicin [E] 90 mg/m^2 BSA plus cyclophosphamide [C] 600 mg/m^2 BSA q21d, followed by 4 cycles docetaxel [D] 100 mg/m^2 BSA q21d) compared to standard chemotherapy with anthracyclines (FE120C: 6 cycles E60 mg/m^2 BSA d1+8, 5-FU 500 mg/m^2 BSA d1+8 and C 75 mg/m^2 BSA d1–14, q28days). The ADEBAR study was the best recruiting study in Germany in this indication group until the end of the trial.
Methods: A standardized questionnaire was sent to all participating centers in order to find out the extent to which treatment strategies and patient care are affected by participation in the ADEBAR study. The questionnaire comprised 5 questions: previous inclusion of patients at the same tumor stage in studies, the type of chemotherapy received by comparable patients previously outside the study, change in the intensity of medical care since participating in the ADEBAR study, the increase in knowledge acquired through participation in the study, and changes in the overall quality of medical care.
Results: In the year preceding the ADEBAR study, 63.2% of participating centers had not entered their high-risk patients into a clinical trial. Before participating in the ADEBAR protocol, 44.2% of patients with the same indication had received inadequate therapy by today's standard of knowledge, such as CMF, EC/CMF, or 4 × EC. 59.0% of the centers noted an increase in the intensity of patient care as a result of participating in the study – independent from the care given to patients purely as a result of participating in the study. By being part of an investigators' network, with a regular flow of information via newsletters, study meetings, etc., 80.0% noted an improvement in their professional knowledge in the field of breast cancer. Moreover, 31.6% of the centers reported an improvement in the overall quality of their patient care since the start of the trial.
Conclusion: The results of the questionnaire demonstrate that both medical doctors and patients benefit from participation in clinical trials.

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The influence of mentorship on research productivity in oncology

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Background: Mentoring is the process by which an experienced person provides guidance, support and encouragement to a less experienced person. This project evaluates whether the availability and support of mentors are associated with research productivity in oncology.
Methods: Two electronic mailings of an on-line survey were sent out to 1,009 oncologists who have previously attended one of two educational workshops between 1996 and 2004. The two workshops, located in Vail and Flims, have been sponsored by AACR/ASCO/FECS with the goal of training oncologists in the methods of clinical cancer research.
Results: 322 oncologists (32%) responded to the survey with the following demographics: Vail/Flims (56%:44%); m/f (63%:37%); median age = 37; median year of graduation = 2001; medical oncology/radiation oncology/surgical oncology/others (63%: 11%: 9%: 17%); USA/EU/Canada/others (51%: 35%: 6%: 8%); 65% have other academic degrees besides MD. Of all respondents, 88% currently are engaged in academic research, 47% and 45% have been principal investigators on grants supported by academic/governmental agencies, and by the pharmaceutical industries, respectively. About one-third of respondents currently spend over half of their time on academic research. The self-reported median number of peer-reviewed papers published as main or co-author since graduation from medical school was 8 (range 0–150). In day-to-day work life and career development thus far, 81% of respondents have had the support of at least one mentor, while 19% did not have any mentors. All respondents who did not have any mentors indicated that their career would have benefited from having a mentor, and 94% of those who had a mentor indicated that mentorship was important in their career development. For all respondents, the greatest perceived benefits of having mentors are: to discuss research work and projects, to provide career advice, and to generate networking opportunities. Respondents with mentors are more likely to be currently engaged in academic research than those without mentors. However, having mentors or not did not influence respondents' self-reported Publication onlyn record, or in their success of becoming principal investigators on academic or pharmaceutical grants, even when respondents' year of graduation are taken into account.
Conclusions: Mentorship is considered valuable to oncologists in enhancing their research and networking experiences. In this selected group of oncologists, mentorship has effects on their current involvement in academic research, but not on self-reported Publication onlyn or grant records.