COMPASS – Innovative web-platform developed by OPIS to manage Compassionate Use Programmes

Compassionate use is a treatment option that allows the use of an unauthorised medicine.
The European Medicines Agency (EMA) provides guidelines (Article 83 of Regulation (EC) No 726/2004) through the Committee for Medicinal Products for Human Use (CHMP), but these do not create a legal framework. In Europe, compassionate use programmes are coordinated and implemented by Member States who set their own regulations and procedures through their own National Competent Authorities (NCAs).
The FDA describes this treatment option as Expanded Access Programs and refers to the use of an investigational medical product (i.e., one that has not been approved by FDA) outside of a clinical trial. The Code of Federal Regulation (21 CFR part 312 subpart I) provides general requirements and describes criteria that must be met to authorise expanded access.

Different from "treatment options" where drug candidates (i.e. not yet authorised potential medicines) are used in clinical trials with the aim to steer their development through proof of concept all the way up to market access, compassionate use programmes are often a last or only treatment possibility for patients suffering from serious disease where no satisfactory authorised therapies are available. Potential participation in compassionate use programmes also extends to patients who might not have the eligibility criteria for inclusion in a clinical trial or situations where no clinical trials are available.

Pharma's standing

Compassionate use programmes (CUP) offer a possibility to patients to benefit from a specific therapeutic strategy.
Drug development and the advancement of medical science doesn't happen without enormous investment of time and money in often long and very complicated processes of taking ideas and turning them into viable options for patients in need. There are no sure guarantees and only a very few "good ideas" make it through to becoming effective and safe medicines.

Patients taking part in clinical trials make progress in drug development possible but they are often not the ones benefitting from eventual breakthrough therapies.
If a developed drug (during Phase III or on rare occasions, Phase II) shows potential and may provide a last resort for desperately ill patients, extendible use is made possible for a period up to market authorisation and/or until these medicines become readily available.
Any data related to drug safety and efficacy that emerge during compassionate use programmes cannot be used to favour clinical development of a drug.
Therefore, Pharma companies, who agree to compassionate use, do so for ethical reasons that exclude any commercial scope.

Patient safety
Medicine used in compassionate use programmes must be undergoing clinical trials or must have entered the marketing-authorisation application process. Early studies will generally have been completed but safety profiles may not be fully established.
Nonetheless, patient safety remains high priority and patients participating in compassionate use programmes are strictly monitored to ensure their safety and well-being as much as possible. Each patient is assessed by a medical advisory board and approved by an ethics committee prior to participation in compassionate use programmes.

Physician responsibility
For physicians wishing to enrol their patients in compassionate use programmes, the process has been anything but easy. Up to now, they have had to dedicate huge amounts of their precious time to bureaucratic matters with compilation of forms in paper format that needed signing, filing and shipping, waiting for authorisation from various bodies and taking responsibility for drug tracking.

COMPASS – Innovative web-platform
The need to create a system that combines the possibility of tracing all steps in a compassionate use programme with a user-friendly interface that allows for easier process management by physicians involved, has moved OPIS to design the e-product COMPASS. This digital platform fully manages workflow and all processes very efficiently. Application, authorisation, patient enrolment and drug supply management, all happens through one single platform.
In line with the EMA guidelines, the platform is designed to comply with EU requirements and easily adapt to implement regulations on country level. This independent, web based, modular platform is accessible to password protected and profile specific users.
Highly customisable and extremely user-friendly, the system allows for guided compilation of all documents and a validated audit trail tracks all processes. It is further designed to facilitate drug supply processes and communication to external sources such as depots. Other features include centralised document management with easy document upload, online reporting and a customisable report builder.

Corporate Social Responsibility
OPIS is very pleased to have opportunities to collaborate with Pharma companies on projects that truly make a difference in the lives of patients who are dealing with debilitating illness. A small step in the right direction, corporate social responsibility for OPIS starts with a patient-oriented approach.

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OPIS
A personal touch.