International clinical trials day – a day to celebrate

May 20th marks international Clinical Trials Day, a time to recognise the contribution of the many thousands of trial participants, researchers, companies, sponsors, journals, registries and regulators across Europe that have contributed to some remarkable, life-changing advances in modern medicine, in recent years.

According to the EMA, around 4,000 trials are authorised each year across the EEA and this phenomenal effort, in partnership with other global research partners is transforming the way we care for patients and treat many diseases. Over the last 60 years, life expectancy across the EU has increased by nearly a decade. Since the 1980s, death rates from HIV have fallen by around 80% and since the 1990s, death rates from cancer have fallen by 20%. Hepatitis C can now, in most cases, be cured, and advances in targeted, precision medicines are transforming the way we will treat patients in the future.

There is still work to be done. Clinical Trials represent on average 58.6% of the total development costs of a new medicine. Across Europe we need to continue to shape the regulatory and clinical landscape putting patient safety in the center and reducing the administrative requirements, speeding up the conduct of clinical trials, while reducing costs. We have to attract patients to participate in trials, provide them with meaningful, jargon-free information and transparent lay summaries of trial results. To devise meaningful lay summaries, EFPIA is organizing together with EFGCP, EPF and EATG, EGAN and Harvard MRCT a workshop on 29th May, with the aim of embarking on a discussion that will help develop a vision and framework that address stakeholder needs, while increasing transparency and value for public health.

International Clinical Trials Day also provides an opportunity to reflect on developments over the last 12 months in the public sharing of clinical trial data. Since the publication of the *EPFIA/PhRMA principles for responsible sharing of clinical trial data*, companies have made great progress in developing processes for clinical trial data access schemes, translating principles into practice. We are now seeing data being shared with researchers through some particularly innovative solutions and processes. Companies are also aligning their policies to the new EU Clinical Trials Regulation 536/2014 and the European Medicines Agency's transparency policies: Access to Documents (Policy 0043) and Publication and access to clinical-trial data (Policy 0070).

Looking to the future, clinical trial data will be enhanced by the availability of real world data from patient registries, hospitals and general practitioners. Data will be generated more continuously than ever and have the potential to revolutionise general practice and clinical development. To be able to do so, systems need to adapt for real-time assessment and action. It is critical that European partners in research develop systems to maximise the potential of big data while protecting confidentiality of patient data, to further biomedical research.

While clinical trials are evolving with new approaches, technologies and designs they remain an essential part of medical research as they aim at providing the community with the latest innovative treatments and state-of-the-art clinical practice, while fuelling innovative thinking in the clinical scientists' teams for the benefit of European Patients. They have an often personal, pan-European, even global impact on our health, making international Clinical Trials day - a day to celebrate.