

REGULATORY

NEWSLETTER N.24 October - December 2018

CROMSOURCE is committed to sharing our expertise with our clients and future clients. This reflects the first part of our 'Advise Agree Deliver' motto! In this spirit we have pleasure in making available this issue of our Regulatory Newsletter. This newsletter is put together by our expert regulatory team and tracks the changes occurring in European and US regulations relating to clinical research performed in both medicinal products and medical devices.

The Newsletter is a quarterly publication distributed via email and posted on the CROMSOURCE website. We hope you find this information useful, and welcome feedback, questions and suggestions.

Contact us on cromsource@cromsource.com at any time.

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Abbreviations

Acronym	Definition
AEMPS	Agency of Medicines and Sanitary Products (Spain)
ANSM	National Agency for the Safety of Medicine and Health Products (France)
CAMD	Competent Authorities for Medical Devices
CESP	Common European Submission Portal
CCMO	Central Committee for Research Involving Human Subjects (The Netherlands)
CTFG	Clinical Trials Facilitation Group
CTR	Clinical Trials Regulation (EU): 536/2014
EEA	European Economic Area
EMA	European Medicines Agency
EU	European Union
FAQ	Frequently Asked Questions
FDA	Food and Drug Administration (United States)
GMO	Genetically Modified Organism
HHS	Health and Human Services
HRA	Health Research Authority (UK)
ICH	International Conference for Harmonization
IDE	Investigational Device Exemption
IMDRF	International Medical Device Regulators Forum
IMP	Investigational Medicinal Product
IND	Investigational New Drug
IRASS	The Integrated Research Application System (UK)
IRB	Institutional Review Boards
IVDR	In Vitro Diagnostics Regulation, EU 2017/746
IVD	In Vitro Diagnostics
MD	Medical Device
MDR	Medical Device Regulation, EU 2017/745
MHRA	Medicines and Healthcare products Regulatory Agency (UK)
MS	Member State
NCA	National Competent Authority
QP	Qualified Person
P-NCA	Participating National Competent Authority
Ref-NCA	Reference – National Competent Authority
eTMF	electronic Trial Master File
TMF	Trial Master File
UDI	Unique Device Identifier
UK	United Kingdom
VHP	Voluntary Harmonisation Procedure

NEWS FROM EUROPE: MEDICINAL PRODUCTS

News from the European Commission

GMO requirements for investigational medicinal products

[The European Commission](#) published a document addressing [frequently asked questions](#) related to GMO requirements for investigational medicinal products. The term “GMO” in the document covers medicinal products for human use containing or consisting of both genetically modified organisms and genetically modified micro-organisms. The FAQ document presents answers with interpretation provided by the seven new European Countries: Estonia, Finland, Greece, Hungary, Ireland, Malta and Sweden. In cases, where a common interpretation does not exist across the EU, this is also explained in the document.

The 16-pages document includes questions related to authorisation procedures for the conduct of clinical trials and questions related to the scope of GMO framework.

News from the European Medicines Agency

The source of each news item below is the EMA website: <https://www.ema.europa.eu/>

European Union Clinical Trial Regulation - EMA Management Board update

In October 2018, the [EMA Management Board](#) had a meeting, where among others topics, an update on the quality and status of the ongoing development of the EU clinical trial portal and database was presented. The EMA Management Board was informed that the auditable release/ version of the portal and database (release 0.7) is complete. The release is now in an intensive phase of pre-testing and formal user acceptance testing (UAT7) can start in early 2019. Due to the EMA relocation to Amsterdam, the rate of progress with testing of version 0.7 and bug-fixing the audit will take place after 29 March 2019. Currently, it is expected that after successful completion of the audit the go live version of the EU portal and database will be ready in 2020 and subsequently the [EU CTR](#) will enter into application around third quarter of 2020.

The EMA Management Board said that more precise information on timelines will be provided after the audit.

EMA Regulatory Science to 2025' strategy

The EMA, has published its draft [Regulatory Science Strategy to 2025](#). This is a proposed new high – level plan for advancing the EMA's engagement with regulatory science covering both human and veterinary medicines.

The new created strategy will help shape the vision for the next EU Medicines Agencies Network Strategy (2020–2025). The goals are to seek to offer informed guidance on modern medicines development, facilitate the optimisation of regulatory science and critically assess the benefits and risks of innovative therapies and diagnostics based on new technologies.

The EMA was held a workshop on 24 October 2018 to gather insight from stakeholders on the key areas in human medicines. Stakeholders are also invited to send their comments via an [online questionnaire](#) by 30 June 2019.

Guideline on the content, management and archiving of the clinical trial master file (TMF)

On 6 December 2018, the EMA has adopted [Guideline on the content, management and archiving of the clinical TMF](#) for both a paper and electronic format. The guideline will come into effect six months after publication (**6 June 2019**).

The guideline is intended to assist sponsors and investigators/institutions to manage with clinical eTMF or TMF. The guideline is very important because the TMF includes the essential documents that is used by sponsors, CROs and investigators/institutions for the management of the trial and by monitors, auditors and inspectors to review and verify whether the sponsor, the investigators/institutions have conducted the trial in line with the applicable European legislation and the ICH E6 guideline on GCP.

It spells out how relationships between the legal representatives, contract research organisation (CROs), other third parties and sponsors, and investigators/institutions should be established.

The guideline discusses the TMF structure and contents including statistics and data management documentation, superseded documents, correspondence and the contemporariness of the TMF.

In section related to security and control of TMF, the guideline explains how access to the TMF should be managed, how storage areas should be done appropriate and how electronic TMFs should be ensured.

The guideline also recommends how documents of clinical TMF should be scanned and transferred to other media underling that “Particular attention should be paid when documents are stored on electronic, magnetic, optical or other non-indelible media.” and “The ICH GCP guideline requires that copies (irrespective of the media used) in the eTMF that irreversibly replace originals should be certified copies of the original.”

In terms of archiving, the guideline explains how the process should be managed in case of paper TMF and eTMF and how to proceed in case of change of ownership or responsibilities of TMF.

In addition the guideline has been written prospectively in conjunction with a specific requirements of TMF in the Clinical Trials Regulation (EU) No. 536/2014 and some recommendations will be fully applicable once the Regulation comes into force.

Guideline on the requirements for quality documentation concerning biological investigational medicinal products in clinical trials

This guideline came into effect on **1 November 2018**.

The [guideline](#) addresses the specific documentation requirements on the biological, chemical and pharmaceutical quality of investigational medicinal product (IMP) containing biological/biotechnology derived substances. It applies to cases where no ‘simplified IMP Dossier’ is submitted.

News from Individual Countries

- **France**

Fast Track - new clinical trials authorisation program.

In October 2018, the National Agency for the Safety of Medicine and Health Products (ANSM), the French Competent Authority implemented new clinical trials authorisation program for sponsors called Fast Track. The new procedure has been established mainly to reduce clinical trial authorisation application processing timelines and to prepare the ANSM to be more responsive in provision of the future European regulations on clinical trials.

ANSM has set up three Fast Track options: Fast Track 1 for innovative treatments for patients; Fast Track 2 for implementation of new clinical trials on known substances and recently; Fast Track 3 for innovative therapy medicinal products like gene therapy and cell therapy. The first two systems came into force on 15 October 2018, the third will be applicable early 2019.

Fast Track processing times will not exceed 40 days for Fast Track 1 (the regulatory deadline being 60 days), 25 days for Fast Track 2 (deadline being 45 days) and 110 days for Fast Track 3 (at the present is 180 days). The new programs of authorisation of clinical trials are not mandatory; however, their use by sponsors is encouraged.

- **Poland**

Site contracts no longer required for CTA submissions

Poland’s attractiveness for supporting clinical trials has increased since a [new regulation](#) concerning the model forms of documents submitted in connection with a clinical trial of a medicinal product and concerning the level of payment of fees for submitting an application for the initiation of clinical trial was issued on 12 October 2018. The regulation entered into effect on 18 October 2018. According to the new regulations, a contract for the site is no longer required for the submissions.

In Poland fully executed contracts with the sites had to be available for submission to the NCA and the Ethics Committee, which meant that the time needed to prepare the complete documentation was prolonged sometimes by up to as much as four months. As of 18 October 2018 the NCA and Ethics Committee, instead of fully executed contracts, require a brief description of the financing of the clinical trial, information about compensation paid to participants, Investigators and the Institutions and description of any agreements between the sponsor and the Institution where the clinical trial is being conducted. The documents are not required to be submitted in original. The scanned copy of document with/without signatures is acceptable.

- **Spain**

- **Revision of clinical trials guidance**

The Spanish Agency of Medicines and Sanitary products (AEMPS) revised clinical trials guidance presented in the Q&A format, provides instructions and clarifications on how to conduct clinical trials in Spain in accordance with Royal Decree 1090/2015: [Documento de instrucciones de la Agencia Española de Medicamentos y Productos Sanitarios para la realización de ensayos clínicos en España](#). This guide version is ten and is updated periodically by the Spanish Agency. The AEMPS marked new questions and answers by adding new dates and using red colour.

- **The United Kingdom**

- **The MHRA and HRA partnership in the pilot program**

The MHRA, the British Competent Authority and the [Health Research Authority](#) announced about results of pilot testing a new process that will streamline the progression of Clinical Trial applications and will result in a single UK decision on a clinical trial in accordance with EU CTR. The successful cooperation between parties and initial launch of program made that the pilot is being rolled out to more Research Ethics Committees (RECs) each month, giving a greater number of booking options for sponsors looking to be allocated to a specific meeting. The UK Government has [confirmed](#) that MHRA and HRA will align with the CTR where possible after the UK leaves the European Union.

Although, a capacity in the pilot is limited, the MHRA and the HRA would welcome further applicants to get involved. To submit an application must be sent email to contact.hra@nhs.net including 'combined ways of working pilot' in the subject line.

- **The Netherlands**

- **New CTA template**

In December 2018, the Central Committee for Research Involving Human Subjects (CCMO), the Dutch Competent Authority published a new [Clinical Trial Agreement \(CTA\) template](#) for the Netherlands. The template agreement has been prepared for industry initiated and sponsored clinical trials, with human subjects, conducted in the Netherlands by academic, non-academic hospitals and the Netherlands Cancer Institute Foundation of Antoni van Leeuwenhoek.

"The template can be modified as agreed upon between the Parties for accommodating the correct party structure, study-specific requirements, financial arrangements or any other terms and conditions which are relevant for the purpose of the collaboration. During the negotiations any modifications should be marked and explained."

NEWS FROM EUROPE: MEDICAL DEVICES

News from the European Commission

European Commission published guidance on UDIs

In October 2018, the European Commission published guidance documents on the use of unique device identifiers (UDIs).

The [guidance documents](#) discuss how to deal with UDIs for systems and procedure packs, definitions or descriptions and formats of the UDI core elements for systems and procedure packs, UDI assignment to medical device software, clarification of UDI responsibilities in relation to Article 16, and provisional considerations regarding language issues associated with the UDI database.

EU releases MDR and IVDR implementation Rolling Plan

In December 2018, the European Commission published its Rolling Plan to implement MDR and IVDR. The Plan contains the list of identified essential implementing acts like 'Notified bodies scope of designation' or 'EUDAMED Implementation plan and actions' to be put in place by the European Commission during the transitional period together with relevant information on expected timelines and state-of-play.

The document will be quarterly reviewed in order to provide the authorities and stakeholders with the most updated information.

In addition, the Rolling Plan shall be read in conjunction with the MDR/IVDR roadmap, produced by the Competent Authorities for Medical Devices project (CAMD) in cooperation with the European Commission.

European Commission added six new products to Borderline and Classification Manual

In October 2018, the European Commission released an update of [Manual on Borderline and Classification](#) in the Community regulatory framework for medical devices version 1.20 following the release of version 1.19 in April 2018.

The European Commission added six new products where four are considered as a medical devices under the EU's current directives and two products: 'mattress covers against mites' and 'lubricants intended for body massages and/or sexual intercourse' have not been classified as medical devices.

The Manual is updated at least once a year and represents the views agreed by the regulators, after a broad consultation with stakeholders, on products or categories of products, which have raised doubts.

Other initiatives

IMDRF finalizes three technical documents

The International Medical Device Regulators Forum (IMDRF) opened for consultation three new guidelines which are going to provide globally harmonised principles for medical devices.

[Optimizing Standards for Regulatory Use](#)

The document says that "Standards play a significant role in the design, production, post-production and regulation of medical devices throughout their lifecycle." The IMDRF document undertone that harmonization of regulatory processes around the world is necessary because some standards are "too flexible or unclear in expectations, or do not meet a specific need, either for the market or regulators."

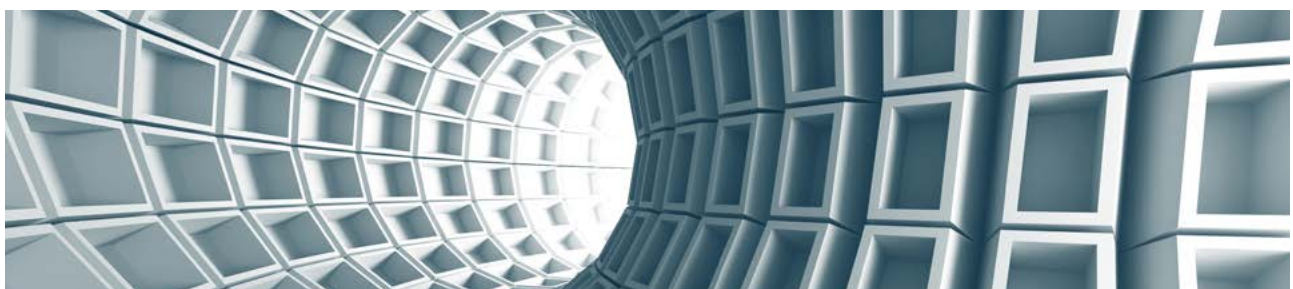
In Appendix B is provided information how to find a contact of a National Body/Committee of each country in the world.

[Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices](#)

"The purpose of this IMDRF guidance is to provide harmonised Essential Principles that should be fulfilled in the design and manufacturing of medical devices and IVD medical devices to ensure that they are safe and perform as intended".

[Definitions for Personalized Medical Devices](#)

The document harmonises definitions for personalized medical devices with presenting several examples of such devices.



OTHER “HOT” TOPICS IN THE EU

Key Brexit updates

The last three months of 2018 year were focused on the political discussion between the European Union and the British negotiators. On 15 January 2019, the UK parliament decided to reject the Brexit Withdrawal Agreement and consequently, according to law, led to the cancellation of transition period for the UK. The UK is due to leave the European Union on 29 March, 2019 regardless of whether there is a deal with the EU or not. The MHRA has published guidance for stakeholders, manufacturers, sponsors and CROs how to proceed if there's no Brexit deal. The main the MHRA proposals to regulate Medical Devices and Clinical Trials of investigational medicinal products, published in January 2019:

Medical Devices

- If no deal Brexit, after 29 March 2019 the European regulatory network for medical devices would not apply in the UK. Medical Devices already existing on the UK market in conformity with the EU Directive will be allowed to stay on the UK market for a time-limited period.
- Labelling requirements will continue and not change.
- The Notified Bodies based in the UK will no longer be recognized by the EU. This means the medical devices UK-based NBs have certified will no longer be in conformity with the applicable EU Directives. Such products will not be able to be placed on the EU market. The MHRA will give UK-based NBs an ongoing legal status and continue to recognise the validity of certificates that they issued prior to 29 March 2019. This will allow medical devices to be placed on the market after 29 March 2019.
- Regarding existing clinical investigation approvals, both for regulatory and ethics approvals changes are not foreseen. UK clinical investigation applications will continue to be authorised by the MHRA and ethics committees as they are presently.
- New Medical Devices Regulations: MDR and IVDR will be applicable in the EU after UK withdrawal of the EU. Nevertheless, the MHRA will bring into force the full application of those two Regulations in the UK and follow transitional timetable.
- “After 29 March 2019, all medical devices, active implantable medical devices, in vitro diagnostic medical devices (IVDs) and custom-made devices will need to be registered with the MHRA prior to being placed on the UK market”

Clinical Trials of investigational medicinal products

- If no deal Brexit, after 29 March 2019, the European regulatory network for clinical trials will not apply in the UK.
- The MHRA and ethics approvals issued before 29 March 2019 will be recognised in the UK and there will be no need to re-apply.
- The UK would require the sponsor or legal representative of a clinical trial to be in the UK or a country on an approved country list which would initially include EU/EEA countries.
- For the UK studies where the sponsor is outside the UK it is recommended by the MHRA to have UK contact point. However, for suspension or termination of the clinical trial the UK legislation allows to submit a notice of it “by the sponsor or the investigator(s) who are responsible for the conduct of the trial at the relevant UK sites”. So, if suspension or termination of the clinical trial UK contact point will be not required.
- For the studies outside the UK, where the sponsor is from the UK, sponsor(s) or legal representative(s) must be based and established in one of the 27th EU countries.
- The current UK (Clinical Trials) Regulations 2004 will be modified using powers under the EU Withdrawal Act (EUWA) to make sure they still work in the UK after exit. The UK Government will re-align with the parts of the EU's CTR legislation that are within the UK's control.



- For IMPs coming from EU/EEA into the UK, the UK will recognise QP certification done in an approved country list which would initially include EU/EEA countries. This means QP declaration will be not needed in the UK, if it has already been certified in one of the countries on the approved country list. When import of IMPs from EU/EEA QP will be required to put in place an assurance system to check these IMPs have been QP certified in the EU or EEA. Such IMPs would not require re-certification. IMPs coming from other countries would, as today, require QP certification in the UK by the Manufacturers Licence MIA (IMP) holder.
- For IMPs coming from UK to EU/EEA is needed at least one QP release site within the EU/EEA for such IMP or comparator(s). QP declaration must be provided an updated according to the EU regulations.
- Suspected unexpected serious adverse reactions (SUSAR) reports would need to be submitted via UK based system to the MHRA. Reporting via the EMA systems (Eudravigilance, Common European Submission Portal (CESP)) will be no longer possible.
- Annual safety reports will continue to be required to be submitted to the MHRA for all UK trials as they are now.
- Clinical trials applications will be continued nationally without sharing CESP in the submission to the MHRA. UK based system will be used, to be confirmed, if IRAS. For ethics submissions using IRAS will be continued.
- “The UK will continue to make information about trials being conducted in the UK available to patients and clinicians via the [UK Clinical Trials Gateway](#). By the time the EU’s new portal goes live (as part of the new CTR), the UK will have its own specific hub that would give both the UK patients and researchers a single reference point for all UK trials.”

The MHRA page will be updated and further instructions will be provided. More detailed information is available here: <https://tinyurl.com/yblnogx2>

VHP procedures in preparation and in case of a no-deal Brexit

In addition to guidance published by the MHRA, the CTFG (Clinical Trials Facilitation Group) published [procedures](#) to be done in case of no deal Brexit in case of Voluntary Harmonisation Procedures (VHP).

- Starting 30 march 2019, the UK will be not eligible to participate in the VHP as a participating national competent authority (P-NCA)
- Any new CTAs where UK is the proposed reference – national competent authority (Ref-NCA) will not be accepted after 22 December 2018. After this date, an alternative Ref-NCA must be proposed.
- Any substantial amendments to ongoing studies with UK as the Ref-NCA will be accepted up until 1 February 2019. After this point, one of the other countries in the VHP will be asked to act as the Ref-NCA.
- All Sponsors or applicants with ongoing VHPs should scrutinise their dossiers e.g. IMPDs for parts that might be affected by Brexit
- All Clinical Trial Approvals after positive VHPs will retain their approval.



NEWS FROM THE UNITED STATES OF AMERICA – “HOT” TOPICS

FDA’s proposed changes to Informed Consent Rules

The US Food and Drug Administration (FDA) back on 13 November 2018 proposed changes that would allow institutional review boards (IRBs) to waive or alter requirements for obtaining informed consent for certain clinical trials involving minimal risk to participants.

Under current FDA regulations, exceptions for obtaining informed consent can only be made in life-threatening situations or when conditions for emergency research are met. Outside those situations, FDA regulations require that subjects provide informed consent before they can participate in a clinical trial.

However, in Section 3024 of the 21st Century Cures Act, Congress expanded the exception to obtaining informed consent when there is minimal risk to participants to FDA-regulated studies.

[FDA Waiver Informed Consent.pdf](#)

FDA is also seeking comment on the types of studies that would meet the criteria for minimal risk that investigators would request a waiver or alteration of informed consent from the IRB.

“To waive or alter informed consent under the proposal, the IRB would need to make findings that have been included in a Common Rule waiver provision for minimal risk research for decades,” FDA says, referring to provisions for waiver of informed consent for minimal risk research conducted or supported by other federal departments and agencies dating back to 1991.

Once final, FDA says the new rule will harmonize informed consent requirements for studies subject to its and the Department of Health and Human Services’ regulations.

In order to waive or alter informed consent requirements under the proposed rule, IRBs will need to determine and document the same four criteria as they would need to in order to waive or alter informed consent under the Common Rule:

1. The research involves no more than minimal risk to the subjects;
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. The research could not practicably be carried out without the waivers or alterations; and
4. Whenever appropriate, the subjects will be provided with additional patient information after participation.

But FDA says it is not adding the fifth requirement that was added to the revised Common Rule set to take effect in January 2019 that allows a waiver or alteration of informed consent for research involving identifiable private information or identifiable biospecimens if the research “could not practicably be carried out without” without using identifiable information.

What Clinical Investigations are affected?

The only clinical investigations affected by the Proposed Rule are those that are FDA-regulated and “minimal risk” – a term defined by FDA to mean that “the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.”

Such minimal risk investigations may be approved by IRBs through an expedited review procedure. Although FDA has designated specific categories of research that may be reviewed through this procedure, the designated activities are not automatically considered minimal risk just because they are on FDA’s list. Rather, inclusion on the list simply means that the research activity is eligible for expedited review where the specific circumstances of the research involve no more than minimal risk.

Still, the designated research categories shed light on the types of studies that may be deemed minimal risk, including: research on a drug or device where an investigational new drug application (“IND”) or investigational device exemption (“IDE”), respectively, is not required; prospective collection of biological specimens for research purposes by non-invasive means (e.g., hair and nail clippings); collection of data from voice, video, digital, or image recordings made for research purposes; and research on individual or group characteristics or behaviour, or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

“Over the years, FDA received feedback from sponsors and investigators that they were not able to move forward in conducting important clinical investigations where there would be minimal risk as these trials involved situations where obtaining informed consent wasn’t possible. FDA Commissioner Scott Gottlieb said in a statement.

Previously, FDA lacked the power to waive the informed consent requirement in these situations. That changed with the passage of the Cures Act in 2016. To ensure the new flexibility is attached to sufficient safeguards, FDA plans to adopt the Common Rule that has been used to protect subjects in studies run or supported by HHS since the early 1990s.

The original Common Rule set out four criteria a trial must meet before an IRB waives or alters the informed consent requirement. The criteria state the trial must involve minimal risk, could not practicably be performed under normal informed consent rules and that the waiver will not adversely affect the rights and welfare of subjects. Whenever appropriate, researchers should provide subjects with pertinent information after participation.

FDA is proposing to copy the Common Rule requirements into its own regulations. In doing so, FDA plans to overlook a recently-added fifth criterion covering the use of identifiable biospecimens or private information. FDA thinks it is best served by just adopting the four original criteria but is open to receiving comments on the merits of that proposal.

Beyond harmonization, the Proposed Rule should pave the way for certain minimal risk clinical investigations to proceed that otherwise would have never gotten off the ground, offering greater opportunities for sponsors and investigators to further their product development efforts and make positive contributions to the public health.

The agency was accepting feedback on the proposed rule until 14 January 2019. However, with the partial US government shutdown that ended on 25 January 2019, likely could be delays and remains to be seen.

Debrief:

- FDA is planning to waive the requirement for clinical researchers to obtain informed consent if their studies poses minimal risk to human subjects.
- The proposed regulatory changes would give institutional review boards (IRBs) the power to alter or waive the informed consent requirements if certain criteria are met.
- FDA put forward the idea as part of its implementation of the 21st Century Cures Act.

About CROMSOURCE

CROMSOURCE is an ISO-certified international provider of outsourced services to the pharmaceutical, biotechnology and medical device industries, specialised in clinical development and staffing solutions.

CROMSOURCE was founded in 1997. Its successful growth over the last 20 years has been built on stability, integrity, and high levels of customer satisfaction, all of which contribute to a high rate of repeat business. We have grown steadily, but responsibly, to become an organisation of over 550 organised and well-trained experts.

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CROMSOURCE supports the full spectrum of clinical development via our Pharmaceutical, Medical Device and Staffing Solutions divisions. We seamlessly move biopharmaceutical products from first-into-human conducted in our exceptional early phase unit, through all subsequent phases of pre- and post- approval research internationally. We also support medical device projects through regulatory planning and execution, to pilot and pivotal clinical investigations in Europe and North America.

Global Reach

CROMSOURCE, with world headquarters in Verona, Italy, is a leading CRO in Europe and the US with a solid infrastructure and operational subsidiaries in Belgium, France, Germany, Poland, Russia, Spain, Switzerland, the UK, the Netherlands, and the US.

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CROMSOURCE is an international provider of outsourced services to the pharmaceutical, biotechnology and medical device industries, specialized in clinical development and staffing solutions.