

IPMPC Response to ANPD Request for Comments on the Regulation of International Data Transfers

What are the current obstacles for companies to transfer data from Brazil to other countries? And from other countries to Brazil?

As an increasing number of countries adopt restrictions on cross-border data transfers, there is a need for interoperability of instruments for enabling such transfers. For example, personal data is collected at sites around the world for scientific research in the field of health and then accessed by researchers around the world. Without interoperability, the practical complexities of enabling such transfers become enormous.

What is the best way to promote convergence and interoperability between contractual instruments for international data transfers with instruments from other jurisdictions? And how can ANPD act in this regard?

The approaches followed in Switzerland and the United Kingdom to adoption of new contractual instruments for international data transfers provide models for other countries. In Switzerland, the Swiss data protection authority recognizes the new EU standard contractual clauses for international data transfers as providing appropriate protection provided they are adapted and/or supplemented as necessary to the specific case. In the UK, the government issued both its own, bespoke international data transfer agreement (IDTA), as well as an international data transfer addendum to the EU standard contractual clauses (UK Addendum). This approach has allowed for organizations only needing to transfer personal data from the UK to other countries to utilize the IDTA, whereas organizations with more complex data flows that also involve transferring personal data out of the EU/EEA have been able to use the EU SCCs in combination with the UK Addendum.

What are the main benefits and impacts of international data transfers, and what are the best alternatives for addressing them in each of the contractual instruments for data transfers included in the LGPD and in international practice?

In order to be able to effectively and efficiently develop, manufacture, and distribute drugs and medical technologies, life science companies need to be able to operate and collaborate on a global scale. Beyond the need to transfer patient data, pharmaceutical and medical device companies that operate globally need to be able to transfer a range of data concerning health care professionals, researchers, support technicians, employees, and others. The continuity of R&D and healthcare services provided by the global pharmaceutical and medical device industries depends upon these transfers.

A. From Research & Development to Product Safety

Today's pressing health concerns require global, concerted efforts to find safe and effective solutions. The COVID-19 global pandemic has highlighted the importance of global cooperation to address the threats posed to life, well-being, and economic prosperity by diseases and pathogens. Through data sharing and collaborative research, biopharmaceutical and medical technology companies worldwide have been racing to develop treatments for the COVID-19 virus and vaccines to limit its spread. However, this is but one example of the need to transfer data around the world to speed the discovery and development of new life-saving and life-enhancing medical products.



i. Global clinical studies

Development of innovative products to treat and prevent serious health conditions and diseases takes years. Products that must be effective worldwide require the input of scientists worldwide. To ensure that new medical products are safe and effective, data are needed from clinical studies that evaluate the use of the new product in patients. Increasingly, clinical studies involve patients and sites worldwide. Why? Global studies ensure that new products are safe and effective across different demographics, and it is more efficient to find a representative sample of trial subjects when you can conduct trials around the globe. This is especially true for studies involving rare diseases and conditions.

ii. Demonstrating safety and efficacy

The data that is generated during global research and development (R&D) must be analysed by experts and used in submissions to health authorities and other oversight bodies worldwide. These submissions are critical to demonstrating that new therapies are safe and effective for their intended uses. Regulators and oversight bodies must receive data that allows links back to the original trial – without those links, regulators would not be able to have confidence in the scientific integrity of the research.

iii. Monitoring and reporting

Finally, regulators and drug manufacturers still need data after a product receives clearance or is approved for marketing. Medicines agencies are charged with ensuring that the drugs and devices used to treat their citizens are safe and effective, and manufacturers of drugs and medical devices have legal and ethical duties to monitor the use of their products in real-world clinical practice and to analyse events and report safety issues to authorities. To meet these responsibilities, companies must be able to collect information on adverse events, wherever they occur, and share this information with all relevant oversight bodies wherever the product is marketed. That way, patients in every country get the benefit of a manufacturer's global experience with their product.

B. From Patient Monitoring to Product Maintenance & Support to Product Customization

i. Seamless healthcare delivery

Just as companies need to be able to transfer data across borders to conduct R&D and monitor product safety, healthcare delivery often also involves data transfers. Modern healthcare delivery relies on the availability and performance of a multitude of medical technologies. These devices are increasingly interconnected and must work seamlessly together to provide healthcare professionals with the diagnostic, therapeutic, and preventive tools they need to deliver high-quality, life-saving medical care. These medical technologies may transmit data to a centralized, global platform that can be accessed by health care providers and allows for real-time healthcare monitoring. They may also be supported by a team of global service provider personnel to ensure continuity of operations and optimal performance.

ii. Remote patient monitoring

Remote patient monitoring technologies have been shown to be effective in managing chronic disease and post-acute care. They can provide health care professionals with information to enable early detection of health events so that proactive interventions can be prescribed. They can also be used to alert caregivers to situations requiring immediate medical attention. Many medical devices on the market today come with remote communication abilities embedded or available as optional



attachments. A central database may be used to cost-effectively provide remote patient monitoring services to health care providers around the world.

iii. Remote service

Remote service is the delivery of hardware and/or software system support, maintenance, and troubleshooting from a location beyond the healthcare delivery organization's site. Remote servicing capability has become common for most IT-based medical equipment. Remote servicing allows an equipment service provider to more efficiently monitor system performance and perform maintenance, enabling early detection and correction of potential hardware and/or software problems that could jeopardize the correct operation or continued availability of the device. It also allows remote service technicians, in the event of a system failure, to assess the severity of the problem and determine possible solutions. This can be critical when a failure occurs during a medical procedure and the healthcare provider requires immediate assistance. Finally, it enables service provider staff to more effectively provide support information and advice when on-site visits are costly or impractical. Maintenance and support of today's highly sophisticated medical devices requires specialized knowledge and training, and a global team of support professionals can most cost-effectively provide this support on a 24/7 basis.

iv. Patient-Customized Treatments

Life science products increasingly require sharing and using patient data so that treatments can be customized to particular patients. From sizing of a prosthesis to tailored therapeutics, there is an ongoing need to exchange patient information so as to optimize healthcare delivery.

Which criteria and/or requirements should be considered in regulating each of the following international data transfer mechanisms and why?

- a. standard contractual clauses;** Please see our comments above concerning the need for interoperability with contractual instruments from other jurisdictions.
- b. specific contractual clauses; and**
- c. binding corporate rules.** Convergence and interoperability is critical in this context as well. The ANPD should consider recognizing companies' existing binding corporate rules approved in the EU, UK, Switzerland, or other jurisdiction with similar data protection standards to those in Brazil, provided that they are adapted, as necessary, to cover data subject to the LGPD.

To what extent should the elements to be considered by ANPD in assessing the level of data protection of foreign countries or international bodies for adequacy purposes (article 34 of the LGPD) also be taken into account within the scope of the rules for contractual instruments?

The ANPD should act swiftly to recognize those jurisdictions that provide an adequate level of data protection. Doing so will allow organizations to focus their compliance efforts on ensuring appropriate safeguards are in place in other jurisdictions where the data processing risks may be greater.

The instruments adopted by the ANPD for enabling data transfers to non-adequate jurisdictions should establish appropriate protection without regard to the location of the recipient and without requiring the user of such instruments to do further analysis of the level of protection.

Should the standard contractual clauses be rigid and with predefined content, or should their regulation allow certain flexibility concerning the text of the clauses, specifying the desired results and allowing changes as long as they do not conflict with the standard text made available?

We do not believe that these different approaches are mutually exclusive. The advantage of standard contractual clauses with predefined content is that negotiation of the clauses can be expedited. For organizations needing to execute standard contractual clauses with hundreds or thousands of third parties, such predefined content that all parties recognize as de jure compliant can avoid case-by-case negotiation of terms. Nevertheless, there are also circumstances where organizations already have put in place contractual safeguards to protect transferred data, and allowing those organizations to continue to rely on such existing contractual safeguards, provided they otherwise meet the desired results, would avoid unnecessary additional contracting. Many large multinational organizations, for example, have put in place global data protection contract terms with their vendors. These contract terms are typically based on EU GDPR requirements, and provided they cover data subject to the LGPD, they should be recognized by the ANPD as providing sufficient protection.

What would be the most appropriate format for ANPD to make available models of standard contractual clauses for international data transfers? Are there any relevant tools that could be used to this end (e.g., decision tree, forms, checkboxes)? Are there any experiences on the theme that could serve as an example for ANPD?

To the extent that the ANPD publishes an option for standard contractual clauses that uses predefined content, we encourage the ANPD to allow such clauses to be incorporated by reference into other general agreements, with any parts of the standard contractual clauses requiring input/choices to be incorporated into a standard table/form. The UK Addendum provides an example of this approach.