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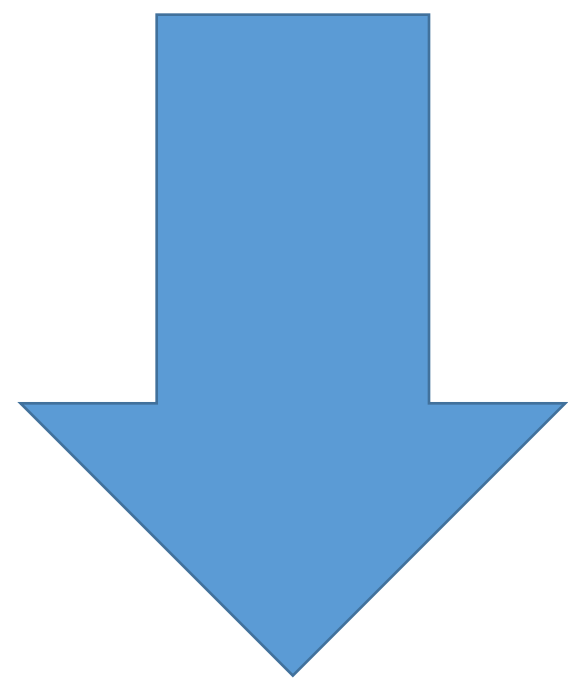
# TRADE SECRETS, INTELLECTUAL PROPERTY AND VACCINES



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## TRADE SECRET



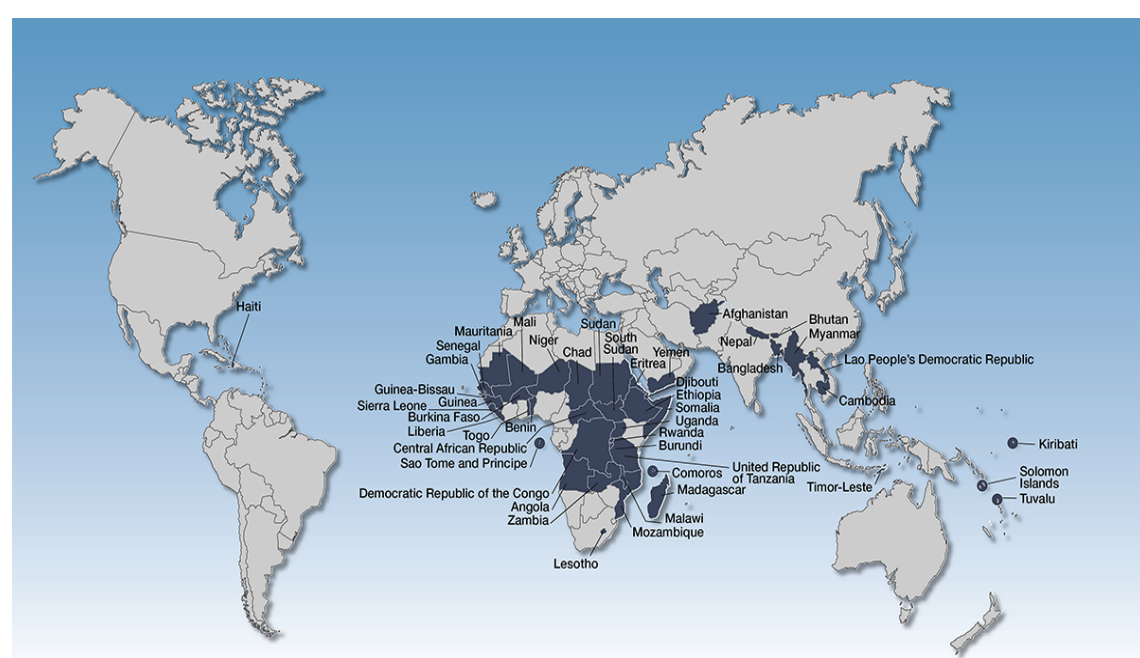
a) it is secret, in the sense that it is not, in the precise configuration and assembly of its components, generally known or easily accessible to people within the environments that normally deal with the type of information in question;

(b) has commercial value as a secret;

(c) has been subject to reasonable security measures by the person who has legitimate control of the information, to keep it secret



**TRADE SECRETS CANNOT BE  
PROTECTED BY PATENT**



**LDCs**



The TRIP's agreements have governed Intellectual property since 1994

One hundred academics have proposed a derogation from these Agreements to allow access to vaccines and treatment even in low income countries (*Least Developed Countries LDC*)

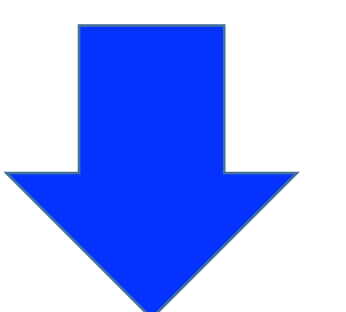
The European Parliament with the resolution of 10/06/2021 expressed in favor of a **temporary modification of the Agreement**

**NO AGREEMENT HAS BEEN  
REACHED BETWEEN PARTIES**

Directive (EU) 2016/943 of the European Parliament and of the Council of 8 June 2016 on the protection of **undisclosed know-how and business information (trade secrets)** against their unlawful acquisition, use and disclosure



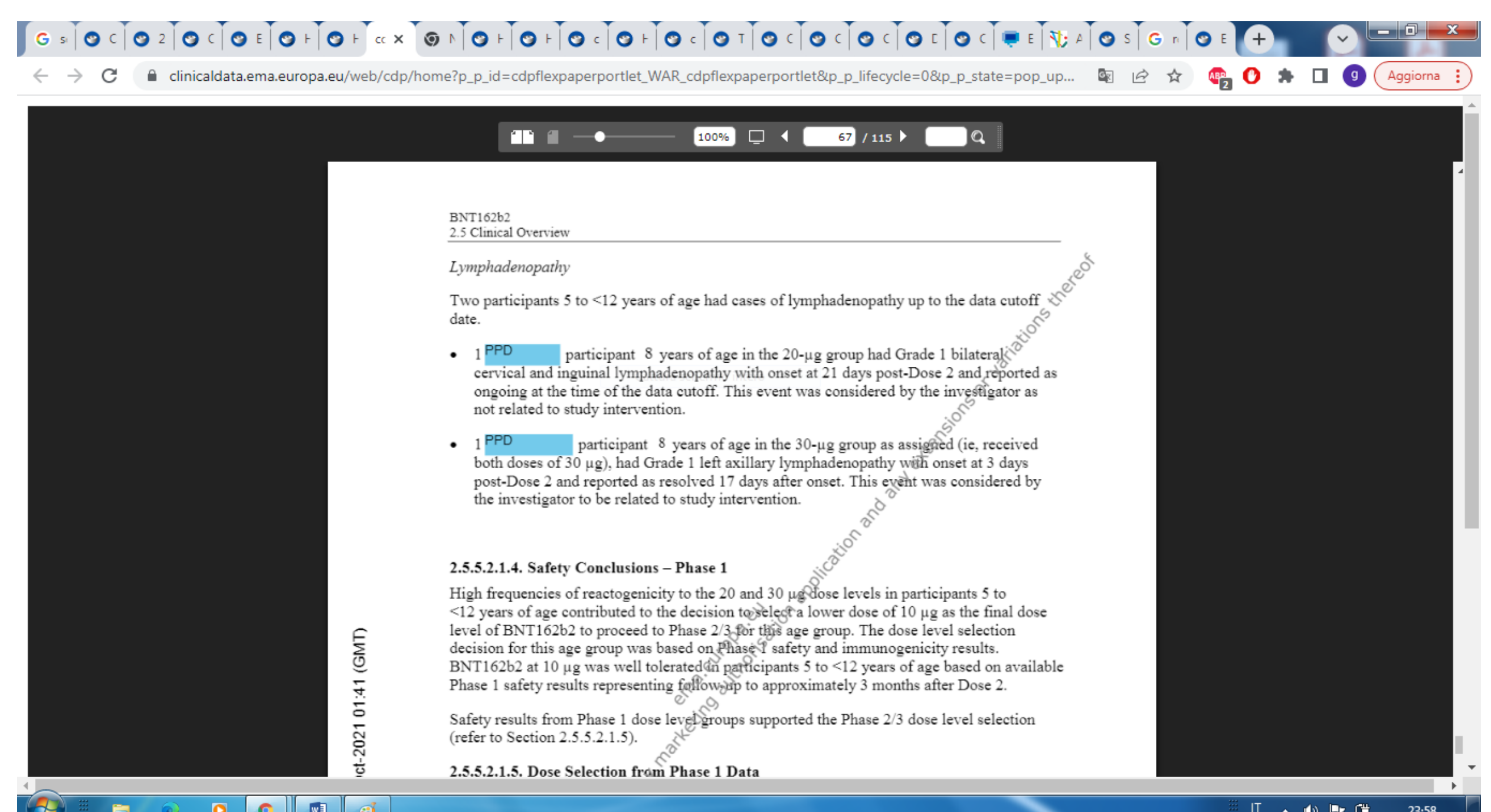
## VACCINES



Following COVID-19 virus pandemic, several vaccines have been developed. During the vaccine development process, **intangible information is obtained that is protected by trade secret**

*The EU Ombudsman considers that, in general, clinical data cannot be defined Confidential Business Information (CCI)*

the clinical reports must be anonymised to prevent patients and professionals who participated in clinical trials from being identified



During the COVID-19 pandemic, the European Medicines Agency (EMA) has implemented exceptional measures to **maximise the transparency of its regulatory activities** on treatments and vaccines for COVID-19 that have been approved or are under evaluation. Trial data have been published on Clinical data website after Marketing Authorisation; **additional trial data have been also published after major changes to authorization.**



## 54. TRADE SECRETS, INTELLECTUAL PROPERTY AND VACCINES

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Know-how is a set of intangible techniques and practices characterized by secrecy such as to provide the holder with an economic advantage. Although this definition is not sufficient to ensure patent coverage, trade secrets can nonetheless be protected under law. EU Directive 2016/943 establishes that trade secrets constitute any information that is: a) secret in the sense that "it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question"; b) has commercial value because it is secret; (c) has been "subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret". The Covid-19 pandemic caused by a new coronavirus confronted the scientific community with a major challenge: developing a vaccine. An immense effort led to the development and subsequent availability of several effective vaccines and therapies, which, however, are not accessible to the entire world population, especially those in middle and low income countries. Since research into and development of a new drug entails intangible knowledge and processes protected by trade secret regulations, one hundred international intellectual property specialists have petitioned for a temporary derogation from the TRIPs agreements protecting intellectual property. With its resolution of 10 June 2021, the European Parliament has also come out in favour of a temporary modification to the TRIPs agreements. However, the parties involved have yet to reach a consensus. This study looks at the possible ways in which the parties could achieve an agreement that would protect their rights.

- DIRECTIVE (EU) 2016/943 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 8 June 2016 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure (Text with EEA relevance)

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