



Impact of Digital Sequence Information on sharing of benefits arising from utilization of Genetic Resources

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Abstract

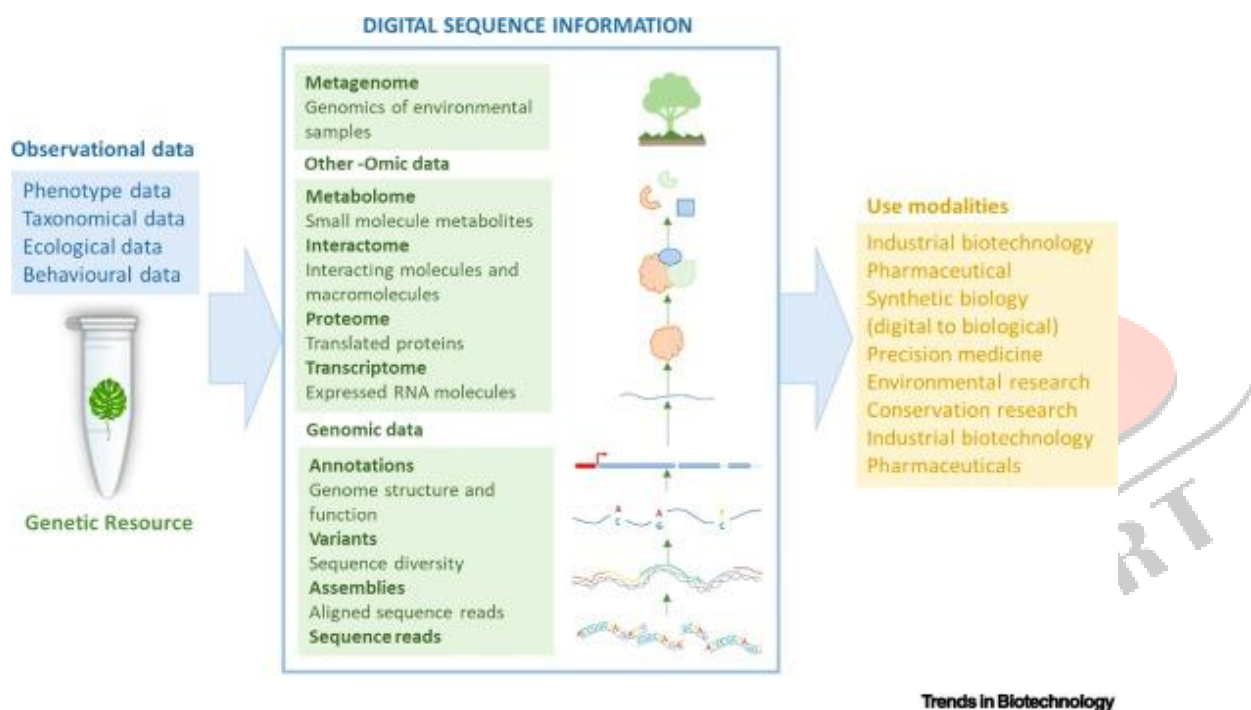
The materialization and evolution of digital sequence information as a speedier, inexpensive and more precise tool, which advances the opportunities as well as challenges for benefits sharing has been followed by the speedy technological advancement. The DSI plays an affirmative role in conservation and sustainable use of biodiversity (i.e., the first two objectives of CBD) and enables the free access to genetic resources without tangibly accessing them. The fact that DSI enables access to genetic information of an organism without physically accessing it, directs much of the emphasis of discussions towards impact of DSI on sharing of benefits arising from utilization of GRs, which constitutes the third objective of CBD, operationalized through the Nagoya Protocol, while acknowledging that the three objectives of the Convention are interlinked and mutually supportive. This Research paper aims to find out the answers of few questions like What is DSI and how is it used? What does this have to do with the CBD and the Nagoya Protocol? How it is impacting on benefit sharing regime? And why is this topic so controversial?

Keywords : Digital Sequence Information, Genetic Resources, Access and Benefit Sharing, Convention on Biological Diversity , Nagoya Protocol.

Introduction:

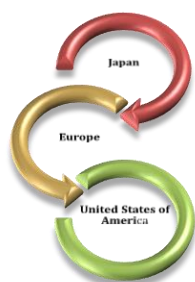
What is Digital Sequence Information?

There are technologies, which are game changer some are widely visible such as smartphones or the internet, then there is Digital Sequence Information (DSI). The result of Sequencing genomes proteins DSI has revolutionized biological science in a way that was unthinkable 20 years ago and still largely unknown to the public but the impact couldn't be bigger. To understand DSI we need to understand the principle of any life on earth every animal, any plant, any other living things carries construction plan within the DNA. DNA is extremely long string of four different chemicals referred to as a . These Chemicals are arranged into genetic code that determines how and organism looks grow and lives. The use of DSI offers wide range of new possibilities such as finding better cures for disease, identifying microorganism that harms plant, adapting crops for climate change and also for protecting endangered species for any of this to happen.



Source: [https://www.cell.com/trends/biotechnology/fulltext/S0167-7799\(20\)30173-6](https://www.cell.com/trends/biotechnology/fulltext/S0167-7799(20)30173-6), last visited on 3rd April, 2021

The Biological resources must have their genes sequences then the sequence information must be stored and made available to the researcher. There are three public database where DSI Information is stored



Unlike the unknown number of private data collection they follow an open access policy and exchange their data. Further more it is also the truth that the bigger the database the better the research. this facilitate the research without the travelling to the different countries of the world. These saves time, money.

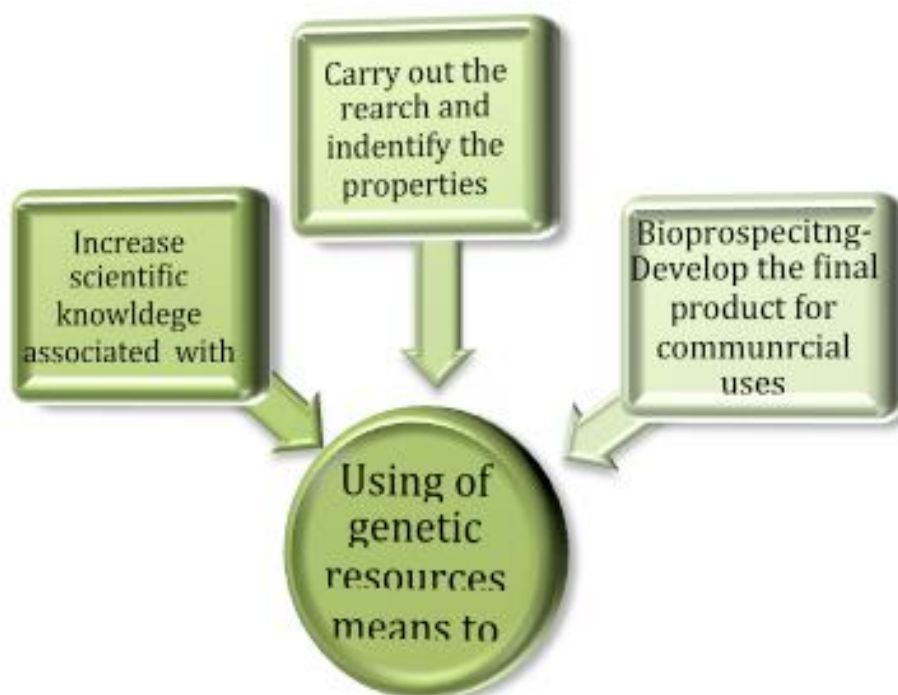
However these also has the adverse effect on the benefit-sharing regime. There are some countries which are concerned that they might lose out on benefit this has caused international dis-agreement about the current DSI system. Although the enormous progress made through DSI is undisputed.

Genetic Resources and Access and Benefit Sharing

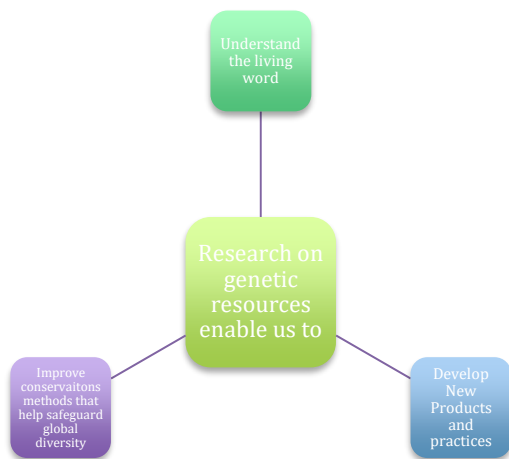
“All living organisms; plants, animals and microbes, carry genetic material that could be potentially useful to humans. These resources can be taken from the wild, domesticated or cultivated. They are sourced from environments in which they occur naturally (in situ), or from human-made collections such as botanical gardens, genebanks, seed banks and microbial culture collections (ex situ).”¹

Significance:

By accessing the genetic resources, it provides the decisive source of knowledge regarding biodiversity. This knowledge can be used in research, for environmental practices and for the producing various kinds of medicines and other human essentials which are at great benefit for the humankind.



¹ Convention on Biological Diversity: ABS. <https://www.cbd.int/abs/infokit/factsheet-uses-en.pdf> last visited on 2nd November, 2020



Every country holds sovereign rights over plant, animals, and genetic resources found in its borders. Any one from another country who wants to use such resources must respect the sovereign right that was agreed upon by 172 countries at the United Nations Rio Summit in 1992. When CBD, The Convention on Biological Diversity was born. The Convention on Biodiversity and its Bonn guideline, Nagoya Protocol defines the ABC of ABS i.e. Access and Benefit sharing compliance of the Access and benefit sharing

The Convention on Biological Diversity (“CBD” or “Convention”) was adopted in 1992, and subsequently opened for signature in Rio de Janeiro during the 1992 United Nations Conference on Environment and Development. The adoption of the Convention represented a major breakthrough after lengthy negotiations over more than three years, under the auspices of UNEP whose Governing Council initiated the process in 1989, building upon preparatory work undertaken by IUCN/World Conservation Union.

For the preservation and sustainable use of the environment and biodiversity United Nations Convention on Biodiversity (CBD) came into force in 1993. The Convention reaffirms the absolute and sovereign rights of the states over their biological resources. Two Doctrines are added to environmental text to understand biodiversity.

This multilateral treaty was adopted with the aim of attaining its three main goals.

- 1) “Conservation of biological diversity
- 2) Its Sustainable use and,
- 3) Fair and equitable sharing of the benefits arising out of use of the genetic resources.”²

The second and third objectives are a clear departure from preceding international biodiversity-related agreements, which were predominantly concerned with conservation. An important aspect of the negotiation of the Convention was the realization that biodiversity rich countries needed to exploit their biological resources for development purposes as well as benefit from the commercial utilization of their genetic resources.

² CBD, Convention biodiversity, 1992

The three ultimate goals of the Convention on Biological Diversity, as articulated in Article 1 of the convention one among them is “fair and equitable sharing of the advantages arising out of the use of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking under consideration all rights over those resources and to technologies, and by appropriate funding”. The Convention on Biological Diversity acknowledges absolutely the and sovereign rights of States over their natural resources in areas within their jurisdiction. Parties to the Convention therefore have the authority to work out access to genetic resources in areas within their jurisdiction.³

According to CBD, Biological resources are the property of the states on whose boundaries these resources are found. These biological resources includes , The ABS system covers all types of genetic resources, be they wild animals or pet animals all kinds of plant, situated on land or any origin of them available in waters of the territory. Human genetic resources are eliminated from the span of application of the CBD. It applies to exploration of resources that are part of in situ or obtained from ex situ laboratories for the research purpose.

The CBD has come up with a procedure for the regulation of accessing the genetic resources and sharing the benefit arising from it. The Third Goal of the convention involves is the joint regulation of accessing the Genetic resources and the sharing the benefit arising out of it. These mechanism is also applicable to Genetic resources, traditional Knowledge associated with .

The Scope of ABS has gotten wider day by day from the adoption of the CBD and Nagoya Protocol and protocol to CBD. Now it covers the diversity in all the aspects of species, genetic resources the traditional knowledge associated with it and also to the DSI.

Understanding Access:

Access to genetic resources is not defined in the CBD or the Bonn Guidelines and, therefore, definition varies according to national legislation and practice. Access may consist of various activities including entering a location or place where genetic resources are found, surveying activities, obtaining or acquiring genetic resources, the use of genetic resources, and the study or systematic investigation of genetic resources for scientific and/or commercial purposes. The Organization of African Unity’s (OAU) African model legislation defines ‘access’ as acquisition of biological resources, their derivatives, community knowledge, innovations, technologies, or practices.⁴

Users endeavoring access such to genetic resources must get the permit from the provider country's responsible national authority except otherwise restricted by that country. This procedure is known as prior informed consent or PIC. These PIC is depends upon the doctrine that the provider should have option to make an decision regarding the giving access to the genetic resources or traditional knowledge associated. This entails the access obtainers to give adequate data and information , in prior to he obtain the access and

³ Earth Summit,1992 – Education. <https://ergautamjain.wordpress.com/2013/11/17/earth-summit1992/>

⁴ http://indiaenvironmentportal.org.in/files/icimod-access_and_benefit_sharing_from_genetic_resources_and_associated_traditional_knowledge.pdf

particular regarding the proposed access action, like the purpose of using such genetic resources and the objects for which the resources would be utilized, so that provider can make an informed decision about permitting or not permitting the access.

Understanding Benefit Sharing

The provider and a user of genetic resources and traditional knowledge must have negotiate agreement for share benefits emanating from the usage of a genetic resource and also for consequent utilization and commercial usage of these genetic resources in a fairly and equitably. This arrangement is recognized as mutually agreed terms MAT. These agreement terms should include only the benefit sharing aspects and also , consequent usage of such genetic resources and traditional knowledge by the third parties with dispute settlement mechanism.

However the Nagoya Protocol does not render specific module templates for drafting such documents, but there are a number of international institutions who have attempted to developed such module template agreements that frame model contractual codicils on which the provider and user of such genetic resources and traditional knowledge may accept upon as a requirement for accessing such genetic resources.

Benefits that are be shared to the provider can be monetary or non-monetary. the convention on biodiversity also has the provision regarding few of these benefits which grants the user Parties to promote and escort study scientific research it also includes the Benefits sharing of benefits which have arose by utilizing the traditional knowledge associated with the genetic resources . The Nagoya Protocol sets the obligation to countries to frame such legislation so that the rights of the provider of such genetic resources and traditional knowledge associates with should be benefitted out of profit aroused out of using the such genetic resources and traditional knowledge for commercial purpose or research purpose .

Benefits can be shared by giving the opportunity to poor or by empowering them by giving them training or educating them for the purpose.

ABS agreements can create non-monetary benefits that enable the local poor. If these agreements are correctly designed, the interest of the local community should take in to consideration and that negotiation procedure should involve the local communities.

Benefits and Beneficiaries

Benefit sharing endures in a monument structure, where the most number of beneficiaries initially benefit, but a significantly smaller number benefit when the activity is at its most profitable. The primary challenge is to allow access for the most number of beneficiaries to benefit (more tangible and intangible benefits) throughout the lifespan of the activity.

Benefit Sharing has been difficult primarily because it depends, firstly, on the amount of monetary benefits being transferred, secondly, on the types of benefits, and thirdly, on the beneficiaries.⁵

Prior Informed Consent and Mutually agreed Terms

To gain access to genetic resources the user must first get the permission from the provider country, this confirmation called the Prior Informed Consent.

The PIC request should outline the nature and intended goal of planned research and utilization.

In addition the Provider and User must negotiate an agreement which includes in detail that which type of benefit being shared and how and when this sharing of benefit will happen. which we refer it as Mutually agreed terms. The MAT will defines the benefit for the provider of the genetic resources as well as further contractual issues.

These benefits could monetary such as lump sum payment or share of the profit or non monetary such as transfer of knowledge, technology or training. These rules applies to commercial users and on basis of special consideration also to non commercial users.

This concept is to help and conserve our biodiversity by sharing the benefits from its utilization in fair and equitable way

Thus PIC and MAT underpin the ABS as they enable provider country to exercise sovereign rights over their genetic resources and negotiate a fair share of the benefits derived from their use

Conference of parties and DSI

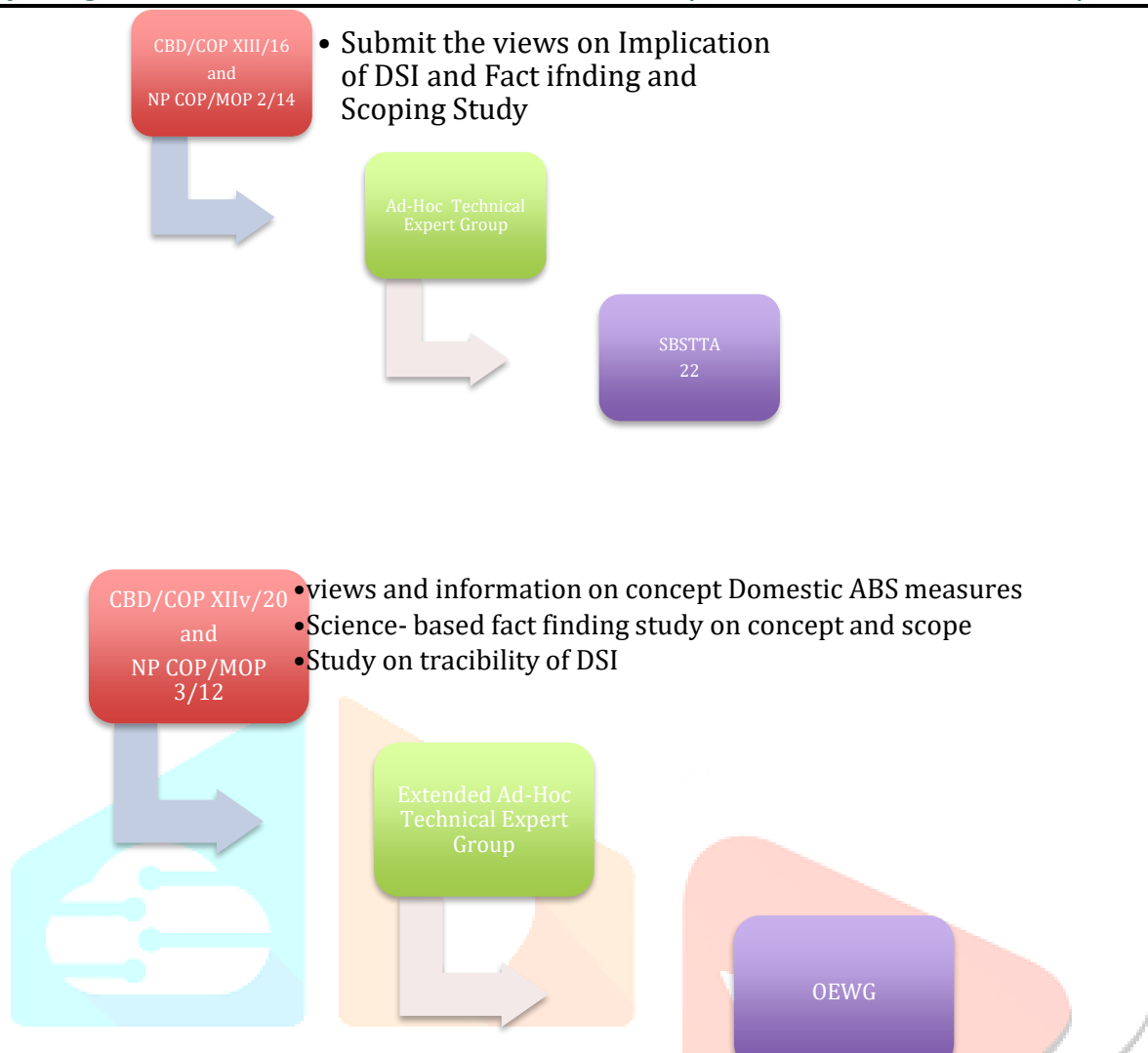
At the CBD's 14th Conference of the Parties (COP) in Sharm El Sheik, Egypt in November 2018, key decisions were made on DSI (Decision14/20) and the comprehensive and participatory process for the preparation of the post-2020 global biodiversity framework (Post- 2020 Framework) (Decision 14/34).⁶ An expert group in 2018 proposed two DSI categories for inclusion: information originating from the physical sample on its genetic and/or biochemical composition, including sequence reads, assemblies, annotations, variants, gene expression, macromolecule data, and cellular metabolites; and observational data, such as ecological relationships, behavioural data, taxonomical data, and modalities of use (Figure 2), providing contextual information and facilitating meaningful interpretation of DSI.⁷

⁵Access and Benefit Sharing issue

https://pharmacy.utah.edu/ICBG/pdf/WebResources/BiodiversityLegislation/ICBG_White_paper_PNG_ABS.pdf, Last Visited on 3, October 2020

⁶ DIGITAL SEQUENCE INFORMATION (DSI), [http://www.abs-initiative.info/topics/dsi/#:~:text=Digital%20sequence%20information%20on%20genetic,their%20Utilization%20\(Nagoya%20Protocol\)%20since](http://www.abs-initiative.info/topics/dsi/#:~:text=Digital%20sequence%20information%20on%20genetic,their%20Utilization%20(Nagoya%20Protocol)%20since), Last visited on 28th march, 2021

⁷ Including Digital Sequence Data in the Nagoya Protocol Can Promote Data Sharing; Jon Ambler, Alpha Ahmadou Diallo, Peter K. Dearden, Phil Wilcox, Maui Hudson, Nicki Tiffin, Published: July 09, 2020 DOI: <https://doi.org/10.1016/j.tibtech.2020.06.009> [https://www.cell.com/trends/biotechnology/fulltext/S0167-7799\(20\)30173-6](https://www.cell.com/trends/biotechnology/fulltext/S0167-7799(20)30173-6), last visited on 2nd April, 2021



- Submit the views on Implication of DSI and Fact finding and Scoping Study
- views and information on concept Domestic ABS measures
- Science- based fact finding study on concept and scope
- Study on tracibility of DSI

DSI and ABS

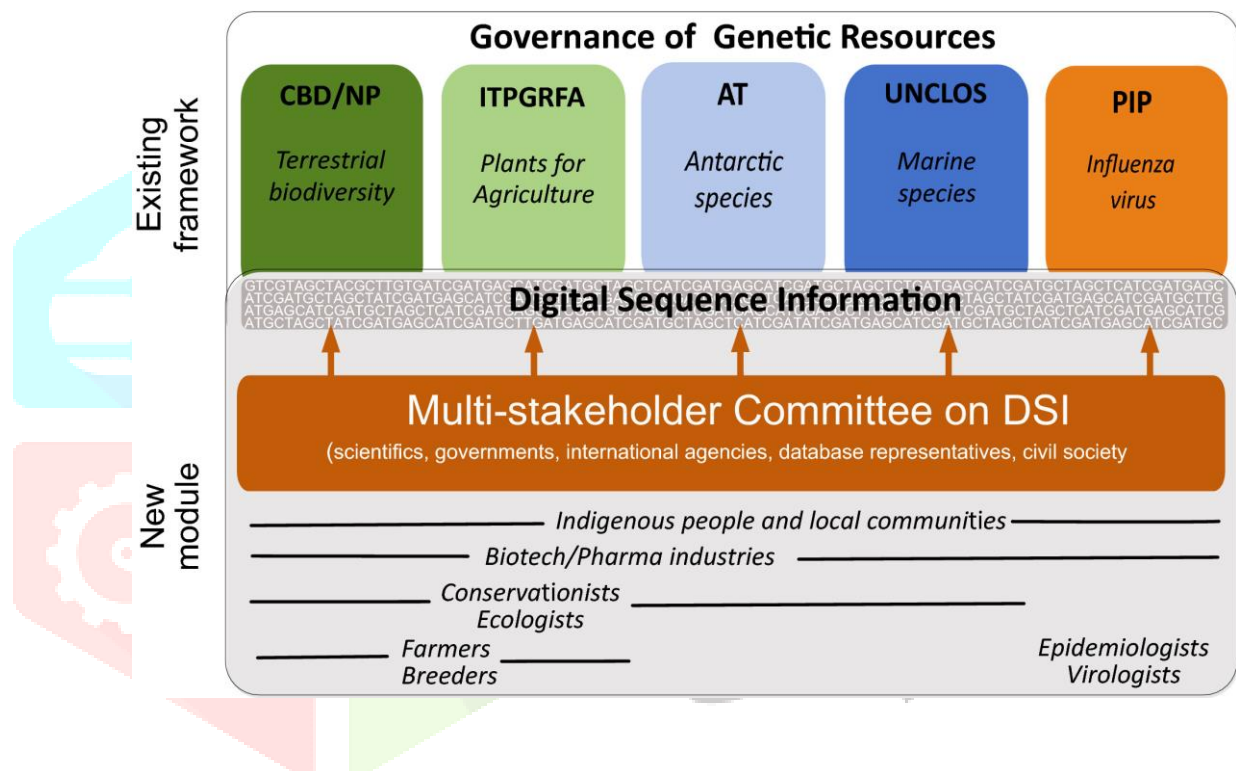
The DSI boons both positive and negative side of as far as biodiversity is concern. It advances and promoted the easy access to biological resources, at the same time it challenges the benefit sharing regime. Moreover, concerns remain that the resources of biodiversity-rich countries in the global South, including sequence information, continue to be used without the fair and equitable sharing of benefits. Challenges for benefit sharing also grow from very different views of the public goods that can be derived from digital sequence information.⁸

The developments in science outlined above have created a situation in which publicly accessible biological data are regularly used for research and development, including by commercial actors, without DSI users having to directly access the original biological material, obtain prior informed consent (PIC) from a provider and

• ⁸ A Fact Finding and Scoping Study on Digital Sequence Information on Genetic Resources in the Context of the Convention on Biological Diversity and Nagoya Protocol, January, 2018 Authors: Sarah Laird People and Plants International , Rachel Wynberg University of Cape Town
https://www.researchgate.net/publication/321005788_A_Fact_Finding_and_Scoping_Study_on_Digital_Sequence_Information_on_Genetic_Resources_in_the_Context_of_the_Convention_on_Biological_Diversity_and_Nagoya_Protocol

share benefits arising from utilization of the samples on mutually agreed terms (MAT).⁹

The debate on the matter that whether the existing international framework i.e. Convention on Biological Resources and Nagoya protocol applies to the Digital Sequences Information if so to what extent it can be included. As DSI advances the open access to genetic resources for the research some countries which are developing and biodiversity rich countries are of view that it should be included in the scope of the ABS frame work. While some developed countries has different approach in this regards.



Source: <https://nph.onlinelibrary.wiley.com/doi/full/10.1002/ppp3.10186>

DSI and Pandemic

Research in pandemic disease would be as successful without the global exchange of DSI. In Covid -19 case the rapid development of vaccine worldwide can not be practically possible before decade. even Ebola virus there is a vaccine. the pharmaceutical company developed the vaccine using the data previously sequenced and uploaded by others. However the company has sold. These vaccine worth hundreds of millions of dollars only to its own government and in Africa where these virus originated this vaccine is still not available.

⁹ Digital Sequence Information on Genetic Resources (DSI); Diverging positions on access and benefit-sharing for DSI http://www.absinitiative.info/fileadmin/media/Knowledge_Center/Pulications/DSI/Introductory_Guide_-_DSI_-_ABS_Initiative_-_201908.pdf, last visited on 27th March, 2021.

Conclusion

The fundamental and radical transition from material to information is exclusive in history. It brings on tons of changes and prospects to the world analysis and use of genetic materials. However, the technological use of DSI in a very apace dynamic scientific setting needs solutions and answers to legal, policy and scientific implications of regulation DSI, that is turning into associate more and more complex challenge. Whereas one may argue that genetic sequences don't fall under the scope of the Nagoya Protocol, since free sharing of DSI may be a common scientific apply which the other resolution would be harmful for world analysis or perhaps dangerous for public health if applied to the pharmaceutical sector, the solution isn't that straightforward. there's a desire for a typical word for DSI on a global, regional and national level, and what ought to be lined by this term.

