DEEP-OCEAN STEWARDSHIP INITIATIVE

DOSI

POLICY BRIEF

February 2022

Traceability of MGR in the New BBNJ Treaty

Key Points

- There need not be a one-size-fits all approach to traceability mechanisms
- Diverse approaches which suit local research and development environments can achieve similar traceability outcomes
- Considerations need to be made in each country regarding potential impact of systems developed on basic research, practicality for achieving traceability objectives and resourcing implications
- Approaches likely to be successful should build on existing global infrastructure or use procedures developed in other policy instruments

Table 1 – Comparing opportunities and challenges for different traceability options

Traceability Option	Opportunities	Challenges
Track and Trace	• Linking with existing compliance measures under national law e.g. reporting, checkpoints, change of use, third party transfer provisions	• Tracing information independently of the physical sample • Gaps and variability of monitoring mechanisms • Compliance burden placed on initial researchers but not end-users • Systems likely to be high cost
Contractual/Licensing	• Standard Material/Data Transfer Agreements (SMTA/SDTAs) can reduce compliance burden by providing standard terms and conditions • SMTAs/SDTAs can be made machine readable, aiding traceability • Machine readable Creative Commons licences could be used for data	• Countries have not agreed on standard conditions under a multilateral system that are consistent across countries • Third party transfer often precluded, increasing burden on researchers to negotiate this on a case-by-case basis
End-user/Product	• Lower impact on research – Obligations for reporting and benefit sharing are only triggered once economic exploitation arises linking end user to provider through various databases (e.g. INSDC, Patent databases)	• Resources and infrastructure required to link end-use to original data and/or sample • Higher reliance on good faith of end-users and accurate/public records of movements and uses
Open Access	• Builds on good scientific practice and existing databases/repositories • Research norms encourage compliance	• Not all collections are globally discoverable or accessible • Better linkages between databases required • Relies on databases and repositories receiving long-term funding
Combined Approaches	• Builds in good scientific practice and uses some existing databases/repositories • Flexibility for choosing possible options	• Includes some of the challenges of traceability options above • Would need to be designed from scratch

Introduction

Marine genetic resources (MGR) from areas beyond national jurisdiction have the potential to be developed to produce products and processes with applications in pharmaceuticals, personal care products, nutraceuticals and biotechnology. These products may benefit humankind in terms of improved health or cleaner and greener industrial processes. Traceability is necessary to connect the eventual product to the original MGR so that any potential benefits can be shared. Benefits can be monetary or non-monetary such as capacity development and technology transfer (Harden-Davies et al. 2020). Traceability can be complex and incorporates aspects of law, science and databases/informatics. This policy brief sets out the differences between track and trace and traceability and then highlights different possible models of tracing MGRs, **Digital Sequence Information (DSI)** and traditional knowledge along the research and development pipeline with a summary table that compares the opportunities and challenges for each model (Humphries et al. 2021, Jaspars et al. 2021).

Comparing Track and Trace with Traceability

There are major differences between systems that rely on track and trace and those that rely on traceability (Figure 1). In a track and trace system, such as an online store that delivers products, the process is set up to trace each stage of the order or delivery process for ordered goods. Some online stores inform the buyer at which stage their order is and when it will be delivered. A system that relies on traceability will employ user due diligence to identify the location of an item. This can be compared to a car recall system. Once a car leaves the factory, the manufacturer will not know where it is located. If a fault is identified by the manufacturer, a recall notice is issued and publicised. Due diligence by the user to check if their vehicle is one with the fault will lead to the user contacting the manufacturer to rectify the fault. Hypothetical track and trace and traceability systems for MGRs being developed into pharmaceuticals are shown in Figure 1.

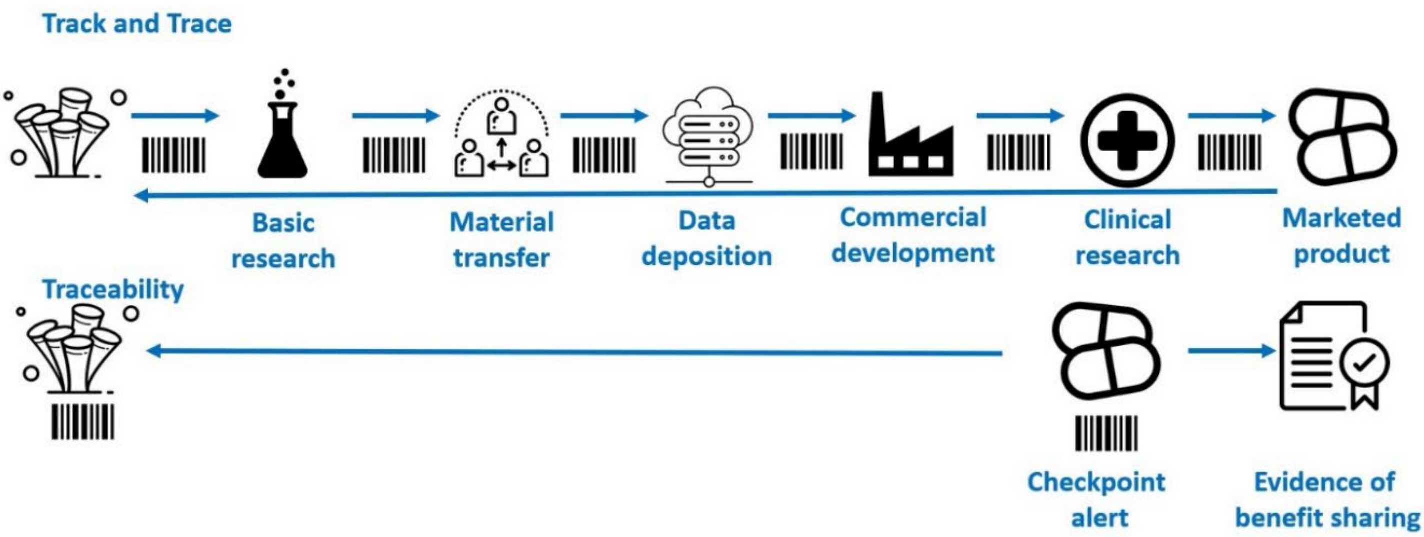

Figure 1. A track and trace system compared to a traceability system. In the track and trace system the exact location of the MGR is known via a database system that is updated at each stage of the process from collection of MGR to commercialised product. In the traceability system, a unique identifier (see also Box 1) is associated with the MGR and is passed between subsequent users. Users should carry out due diligence to ensure they have the unique identifier that may be required for certain checkpoints such as patent applications and publications.

Current Draft Text

The current draft text (November 2019) proposes to cover access/utilisation of MGR and traditional knowledge, sharing of benefits, monitoring and intellectual property but there is little country agreement on the content. It contains a proposal to establish a clearing house mechanism that would collate information from users of MGR on collection activity/locations and where the MGR are currently stored. It proposes that collection of samples be subject to a notification procedure and the deposit of samples, data and related information in open source platforms, that *ex situ* access to MGRs be 'free and open', that access to digital sequence information (or another term for intangible elements of MGR) be 'facilitated' and that traditional knowledge be accessed with the prior and informed consent of the knowledge holders, without any detail of how these procedures would be achieved. The draft text addresses traceability and suggests the use of legal identifiers but the way in which it is proposed means that much of the burden falls on the initial user and not the end user of the MGR (see Box 1). This means the initial user would have ongoing reporting obligations as well as the added burden of assigning unique identifiers and making data and samples available in open access databases and collections. Benefits that might arise from such a system are unclear and how they will be shared between countries needs to be addressed more clearly.

Box 1 – Administrative vs Scientific Identifiers

Scientific identifiers are an essential component of traceability and allow for connectivity between databases. For them to provide stable links, they need to meet criteria such as persistence, authority, and uniqueness. Scientific identifiers like Digital Object Identifiers and globally unique identifiers in biodiversity databases like OBIS have many of these features. In the case of the International Nucleotide Sequence Database Collaboration, accession numbers are allocated to sequences upon submission and represent a unique identifier for any sequence within the INSDC system and is therefore key to traceability. These numbers are cited in resulting publications and also as machine readable links in some cases.

These scientific identifiers are very different to administrative identifiers created for the purpose of ABS monitoring and compliance. Administrative identifiers will be different for each country that relies on them in their governance and regulatory arrangements. The Nagoya Protocol has administrative identifiers linked to access permits and Internationally Recognised Certificates of Compliance (IRCC). These do not follow the movements of the physical materials or traditional knowledge between users because they are linked to the authorisation, but they can be manually updated by the country that issued the IRCC. They are not automatically linked with a scientific identifier relating to the physical materials or DSI.

Track and Trace Option

The *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity* applies to MGRs located within national jurisdiction but its traceability infrastructure (clearing house, certificates, checkpoints, checkpoint communiques and user compliance measures) has relevance for a track and trace approach. As part of this infrastructure, a country issues an internationally recognised certificate of compliance (IRCC) and the Access and Benefit Sharing Clearing House (ABSCH) assigns an ABSCH Unique Identifier, which is attached to the certificate and not assigned to the actual genetic resources that are the subject of the authorisation. Amendments to the records can be tracked by adding a revision number to the ABSCH Unique Identifier. As of 15th February 2022, there are 3483 IRCCs recorded on the ABSCH site, but there is little information about the movement or physical location of the genetic resources after the ABSCH Unique Identifier is assigned. There is little published information about whether or how countries with ABS laws manage the usage of identifiers to trace the materials and/or associated information under their monitoring frameworks within and between jurisdictions in practice. The Nagoya Protocol's traceability infrastructure largely relates to tracking whether Prior Informed Consent has been obtained and Mutually Agreed Terms (benefit sharing) have been established in accordance with national law (but not whether a user has complied with the terms of the agreement). There is very little information about how effective track and trace approaches are for recording the movements of intangible elements of biological resources, namely the use of DSI and traditional knowledge.

For a pure 'track and trace' system (Figure 2) to work in the BBNJ context, national measures arising from BBNJ treaty obligations would need to establish a range of interconnected infrastructure that traces every step from collection to final product of samples and data by each user in every jurisdiction they move through (from ABNJ to national jurisdictions and between national jurisdictions). Blockchain is attracting attention as a potential platform for recording objects, providers, users and ABS terms and conditions across national jurisdictions. However, all countries using MGR and associated data and traditional knowledge must have the technological capacity to interact with the blockchain infrastructure, such as creating, accessing and approving smart contracts as a basis for linking subsequent users to the original terms and conditions of access. It is unclear whether using blockchain for traceability is practical and cost effective and whether its environmental impacts would uphold conservation and sustainability objectives of the treaty.

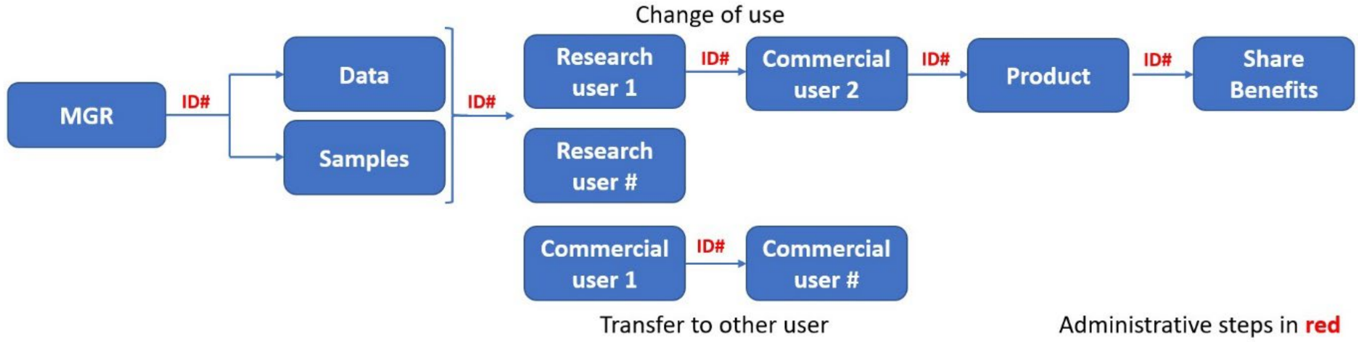

Figure 2. Track and trace option showing how due diligence is required at each step to update a central database with the unique identifier to ensure that current user and location of MGR is known.

Contractual/Licensing Traceability Option

Figure 3 highlights how contractual mechanisms can accompany the movement of materials and associated information and traditional knowledge across jurisdictions and be used for traceability purposes. In particular it identifies how standardised material transfer agreements (SMTAs) (including data transfer agreements), and other contractual mechanisms attach terms and conditions to the transfer of genetic resources/information and the role these may play in traceability.

With machine readable technology, it is possible to incorporate contractual obligations for specific information associated with MGR. One is the use of a standard creative commons licence as a monitoring tool (Scholz et. al. 2020). This would be a legally binding agreement requiring people who are submitting data to a database or MGR to a repository to enter a standardised licence identifier into a metadata field linked to an online version of the licence. Users would bear responsibility for keeping track of the licences associated with the MGR or data they are using, which would be less onerous for a standardised licence than case-by-case benefit sharing and monitoring conditions. This builds on creative commons licences (already in widespread use in science for publishing research findings) and depends on machine readable technology and interoperability of databases.

Following the approach of Standard Material Transfer Agreements (SMTA) used in the Food and Agriculture Organization of the United Nation's *International Treaty on Plant Genetic Resources for Food and Agriculture* (Plant Treaty) and the World Health Organisation's Pandemic Influenza Preparedness (PIP) Framework, Data Transfer Agreements with standard terms and conditions could be an option, particularly if it is combined with a SMTA like the **MicroB3 model agreement**. Again, its usefulness would depend on machine readable technology and interoperability of databases.

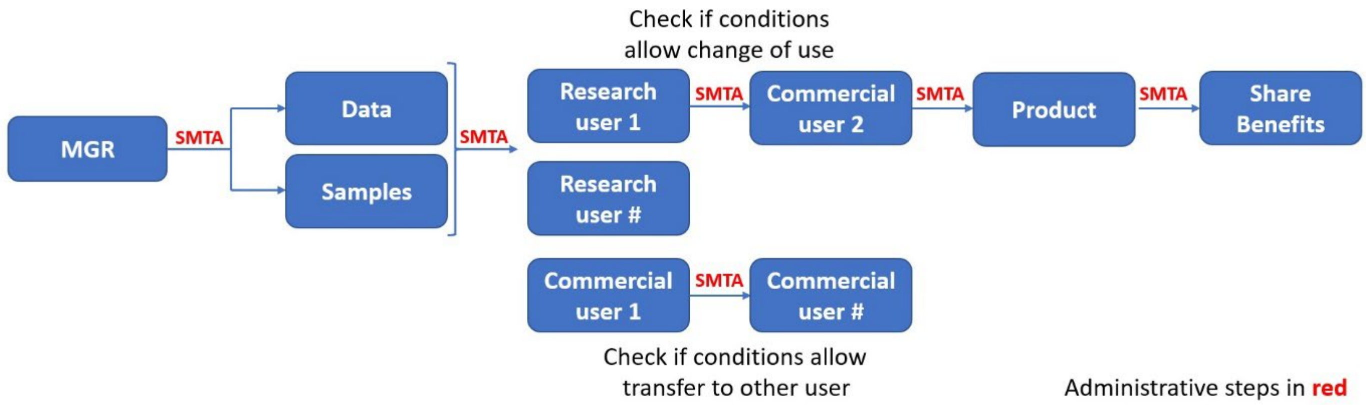

Figure 3. Contractual/licensing traceability option. Standard material/data transfer agreements allow transfer of MGR material/data between users. Due diligence by the users is necessary to ensure that they keep track of the SMTA/SDTA for the material/data they are using.

End-User/End-Product Traceability Option

In contrast to 'track and trace', emerging registration systems relevant to genetic resource/information use offer an approach to traceability that does not require every movement to be traced between users and subsequent users. Instead, they require downstream users to report products or activities at which time certain disclosure, reporting and/or benefit sharing obligations are triggered. An example of an end-user approach is Brazil's ABS law where online self-registration must be completed not at the time of access but prior to a specified event such as commercialisation, intellectual property applications and public disclosure of results concerning Brazil's genetic heritage (including DSI). While access to traditional knowledge still requires prior informed consent, the approach for genetic heritage marks a shift from regulating access activities to regulating economic exploitation of end products arising from access.

End-product traceability options are demonstrated by the increasing number of jurisdictions with disclosure of origin obligations under their intellectual property frameworks. These vary in how they work but essentially it requires an inventor of an end-product to disclose the origin of any genetic resources or associated information used to create the invention in a patent application. There are other forms of intellectual property that could help to link end-products with original materials or information such as trademarks and geographical indications, which may give away the origin of materials in the name. For example, Champagne and Roquefort cheese in France.

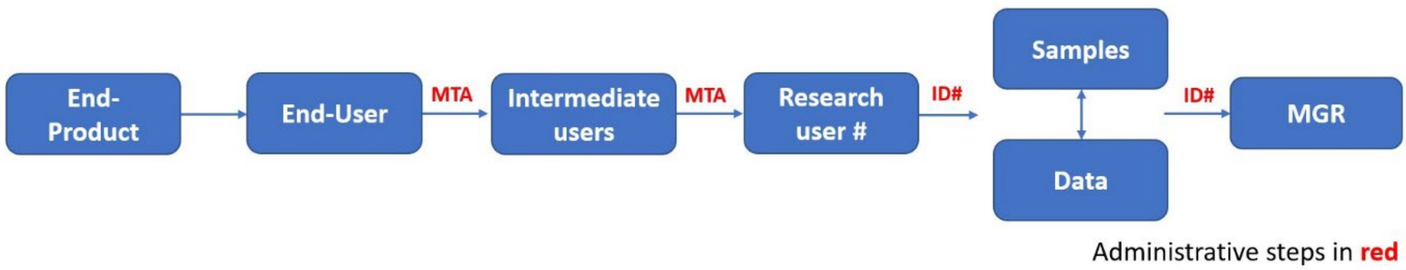

Figure 4. End-user/end-product traceability option. MGR users must report certain events (e.g. products/activities) after which certain disclosure, reporting and/or benefit sharing obligations are triggered.

Open Access

Open access to samples and data can mean a range of approaches in practice, ranging from unrestricted use free of charge for anyone to access with certain conditions. Open access does not necessarily mean that traceability is undermined. The research community has a long history of **open access approaches** to samples and data. Regarding sample sharing, natural history collections have long been available to the science community with traceability through accession numbers or registration.

Figure 5 is a generalised scheme showing marine sampling and bioprospecting where samples as well as data are being considered, and traceability is based on a unique identifier. Using the idea of a bulk identifier for a collection event of physical materials as a practical measure that recognises how research is actually conducted at sea.

Many MGR samples are sequenced as part of scientific research, providing DNA sequence data (DSI). The International Nucleotide Sequence Database Collaboration allocates accession numbers to DNA sequences upon submission, and these, combined with origin information in the accession's metadata, links the sequence with publication digital object identifiers and entries in other related databases. Many journals now require disclosure of source data, which aids traceability of open access samples and data. While there are initiatives in several countries to build traditional knowledge databases, they are often subject to restrictions to protect the knowledge and knowledge holders.

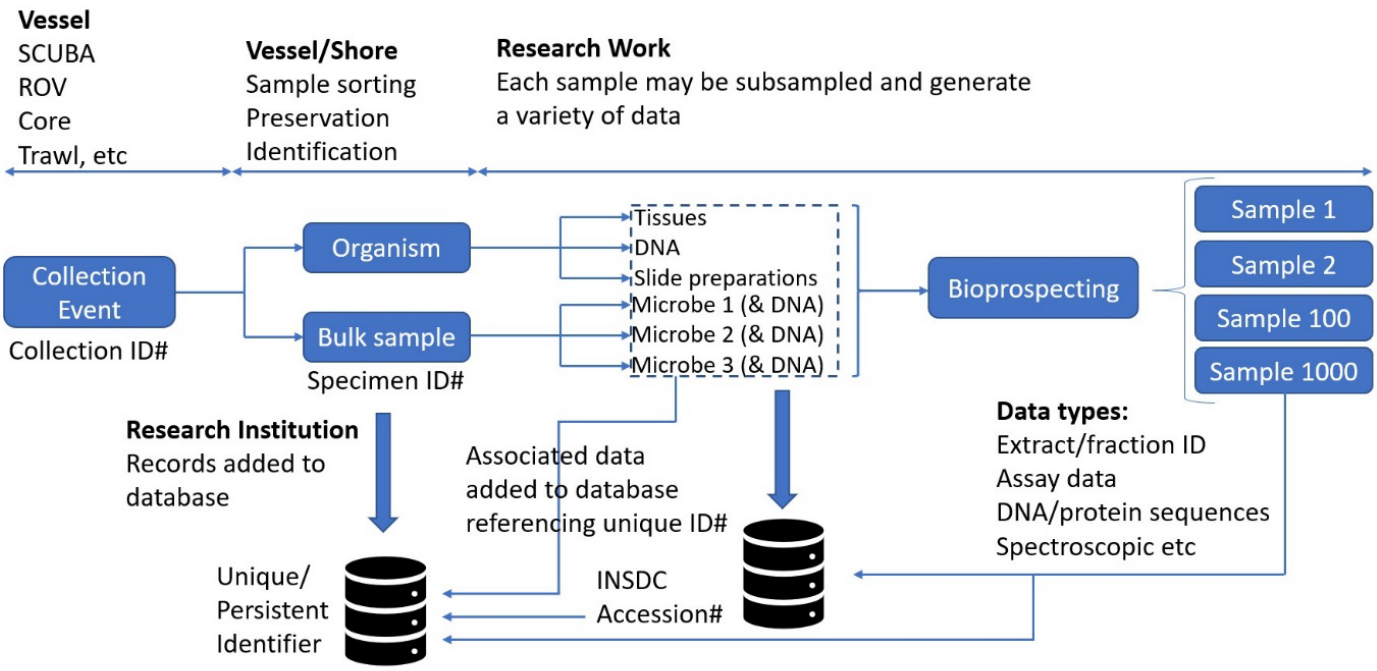

Figure 5. Elements of open access in the marine bioprospecting process showing the importance of scientific unique identifiers in tracing data and materials.

Combined Approaches to Traceability

Policy makers may decide to move away from a one-size-fits all approach to MGR traceability and instead adopt a combination of traceability approaches and infrastructure with standard options for a subsequent user depending on the activity or resource. Such options might include open access, contribution to a multilateral benefit sharing fund, a capacity building database or an end product/user model as outlined below (Figure 6). Another option is a subscription or tax model, requiring payments as a form of benefit sharing that is disconnected from access, either by users accessing the resources (e.g. PIP Framework) or an impost on contracting parties (e.g. Norway seed sales tax). Two combined approaches in the BBNJ context are the OPEN Approach and the Tiered approach (Broggiato et al. 2018, Humphries et al. 2020).

Importance of Incentives for Traceability

Market-based incentives could harness consumer demand for more transparency and sustainability along value chains. Initiatives like the Union for Ethical BioTrade's verification and certification programs for biodiversity-based ingredients promote compliance with legal requirements on ABS, establish broader voluntary measures for benefit sharing along supply chains, and allow companies to communicate on their commitments, efforts and achievements. Scientific incentives are already in operation with many journals requiring disclosure of source data and the inclusion of accession numbers in publications.

Private sector social licence mechanisms include building on the **United Nations Global Compact** model, which provides a universal language for corporate responsibility and a framework to guide all businesses, including a principles-based approach to sustainable ocean business. The sustainable ocean principles supplement the Ten Principles of the UN Global Compact and cover: ocean health and productivity; governance and engagement; and data and transparency.

MGR traceability and benefit sharing could be tied more clearly to work done in achieving the Sustainable Development Goals (SDGs) or the Post 2020 Global Biodiversity Framework, giving countries an opportunity to showcase their commitment to equity and conservation objectives for MGRs from ABNJ through their Voluntary National Reviews for example.

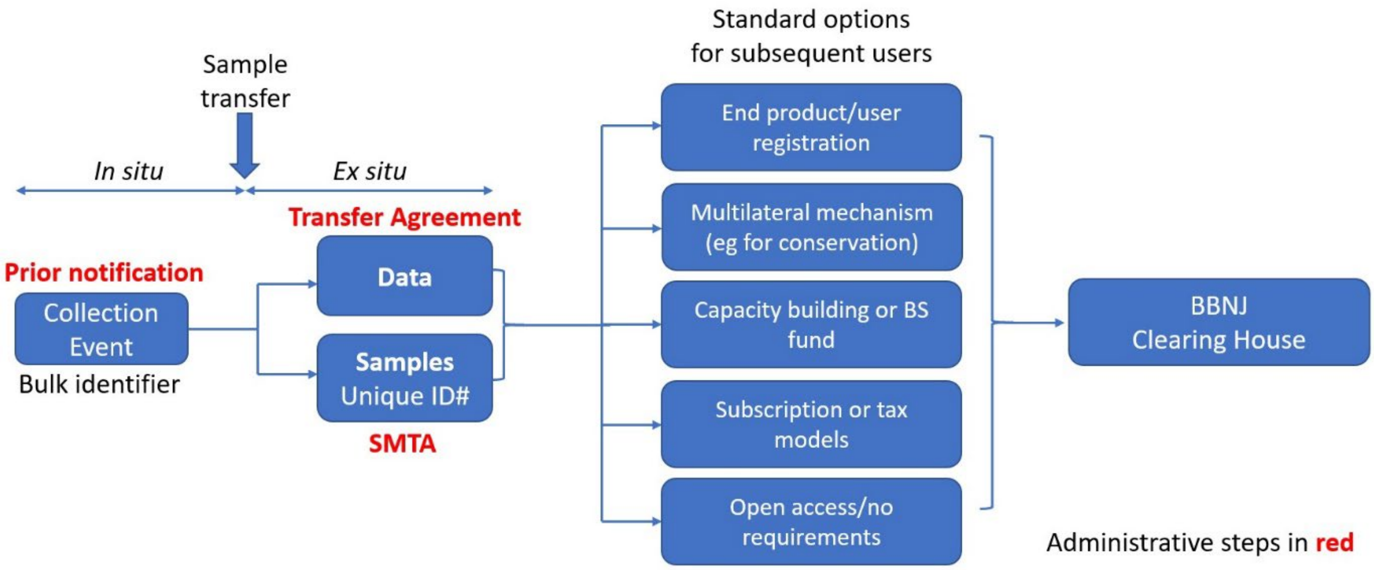

Figure 6. Combined approaches to traceability showing standard options that could be considered for benefit sharing.

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ABOUT DOSI

The Deep-Ocean Stewardship Initiative seeks to integrate science, technology, policy, law and economics to advise on ecosystem-based management of resource use in the deep ocean and strategies to maintain the integrity of deep-ocean ecosystems within and beyond national jurisdiction.

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