

# The ABS/NP and infectious diseases

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Leiden, The Netherlands



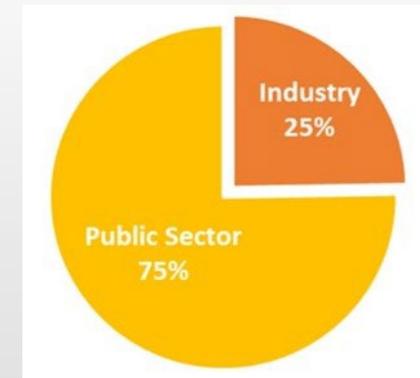
**Dr. Scarlett Sett**  
**ABS compliance officer – European Virus Archive**



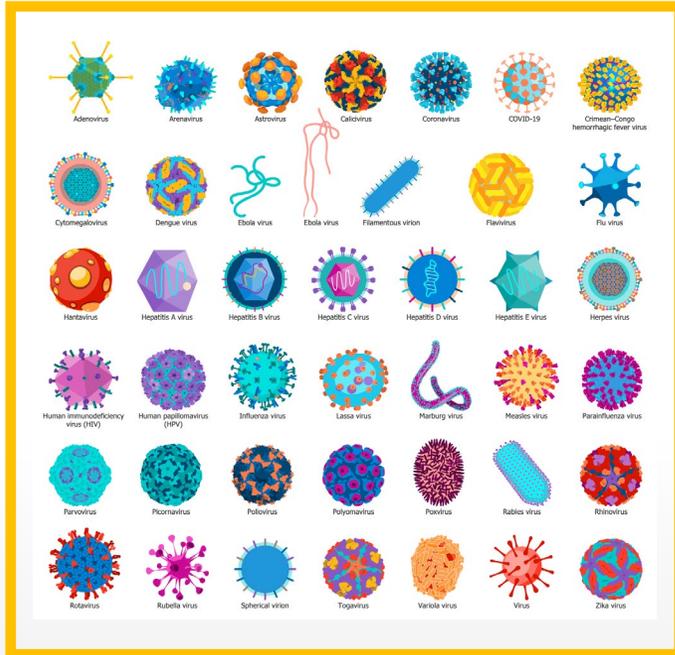
# EVA's role during COVID19 pandemic



- **ABS compliance strategy**
  - country of collection and date of collection (46% → 93%)
  - ABS permits link to items (on-going)
  - improves usability and legal certainty of products for end users
- **Voluntary compliance of non EU partners**



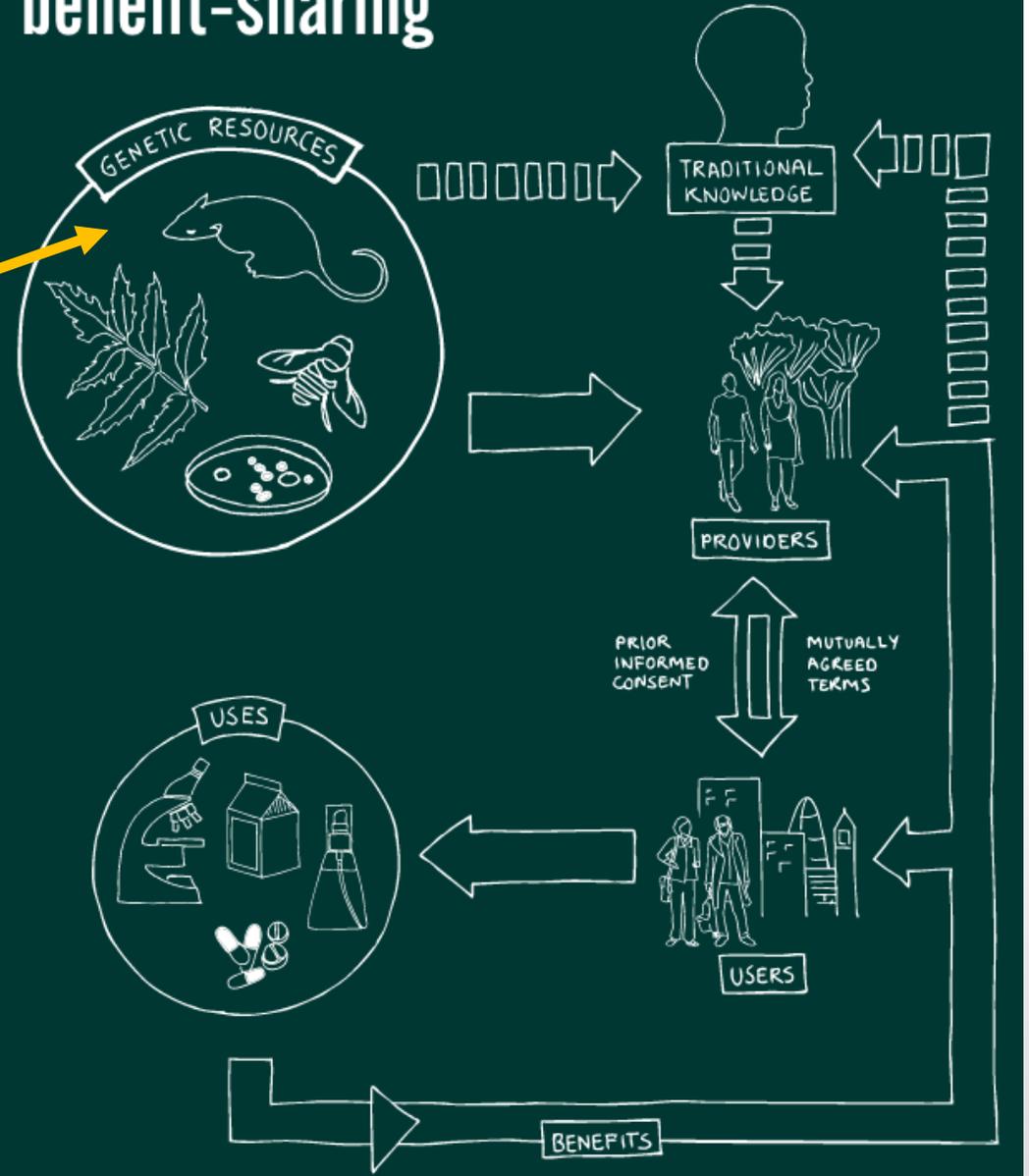
# Pathogens within scope of the NP



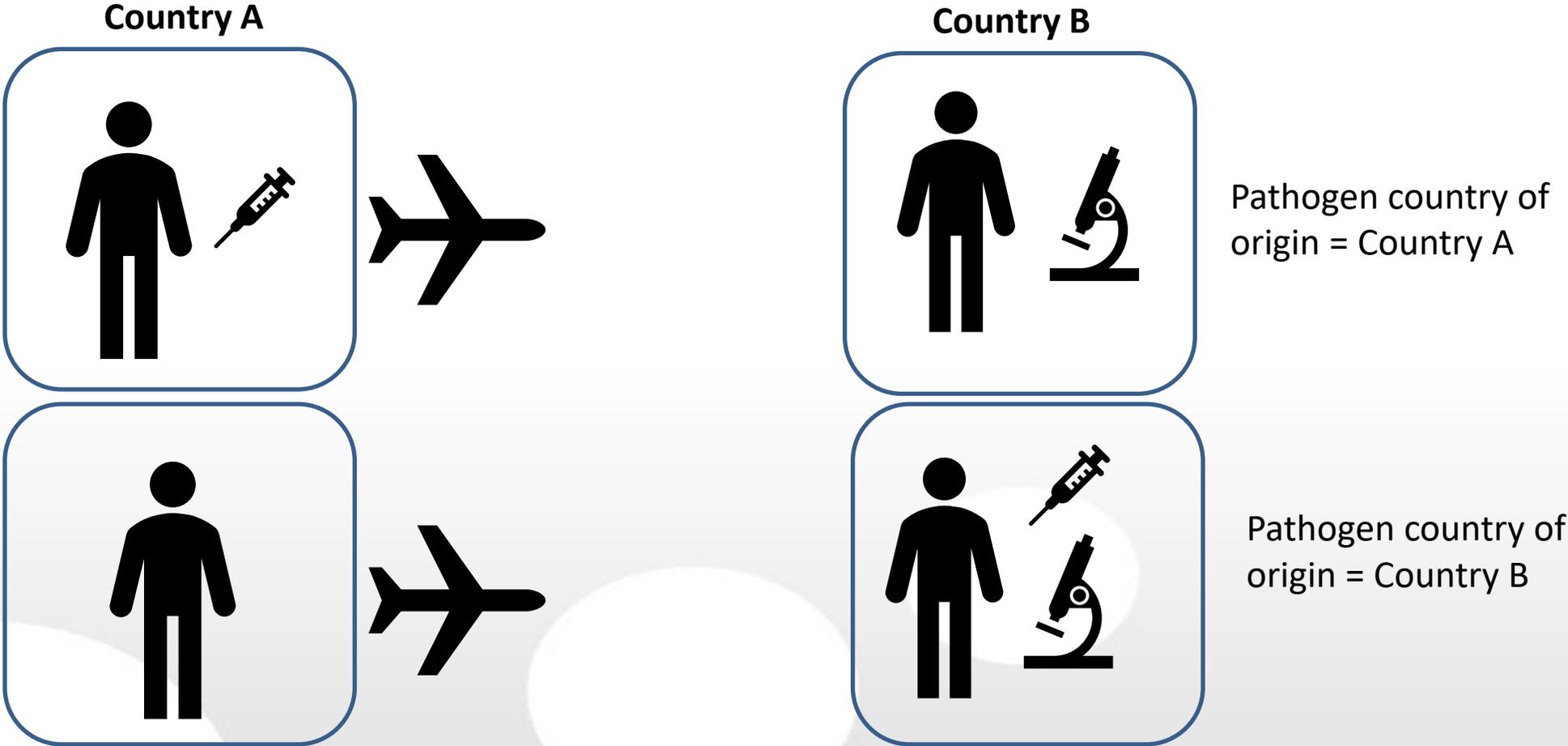
pathogens

- Pathogens included in the CBD/NP
- Country-specific regulation

## Introduction to access and benefit-sharing



# Intentional vs. unintentional introduction according to the EU ABS regulation 511/2014

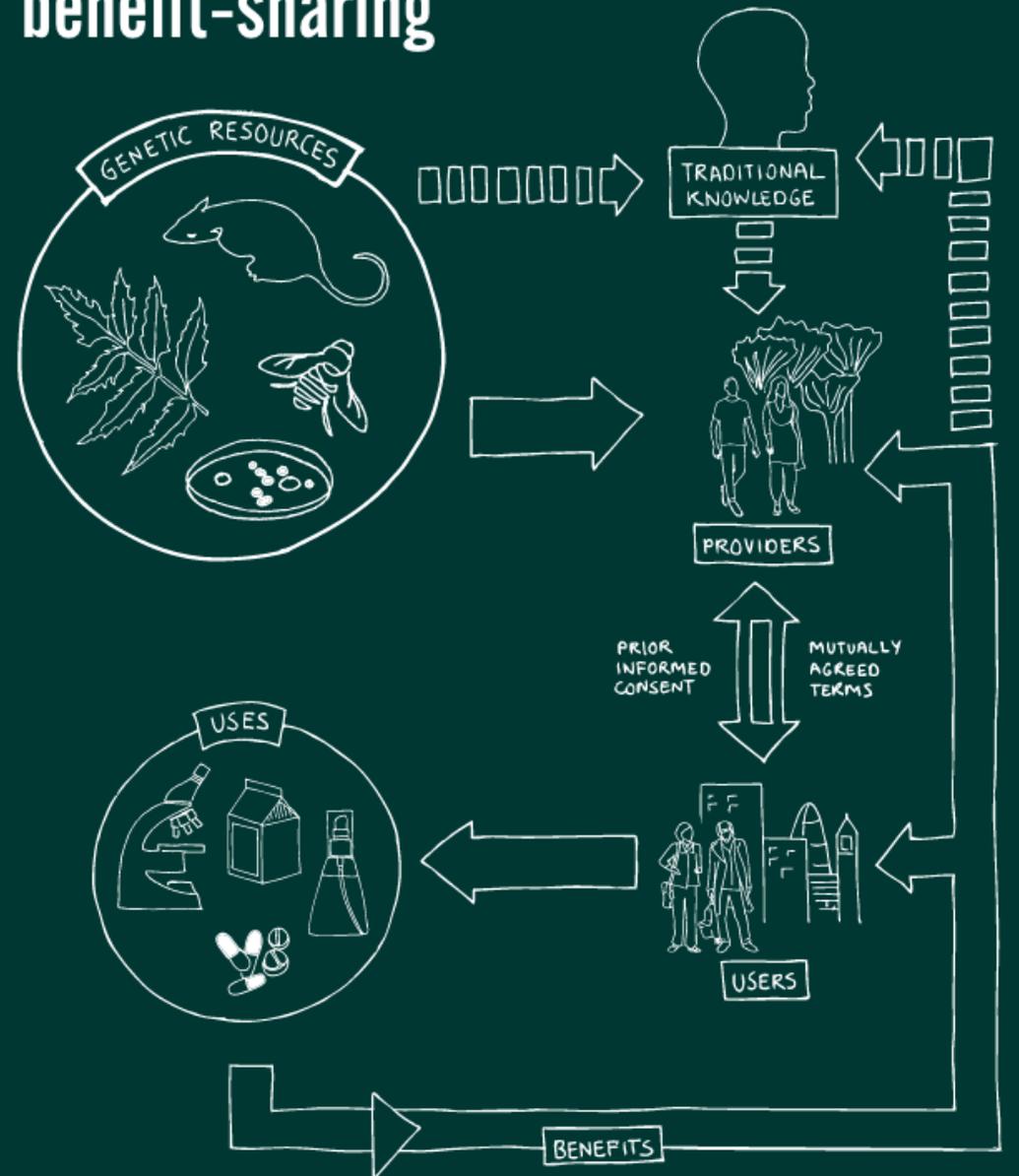


\* Same principle applies to animal and plant pathogens

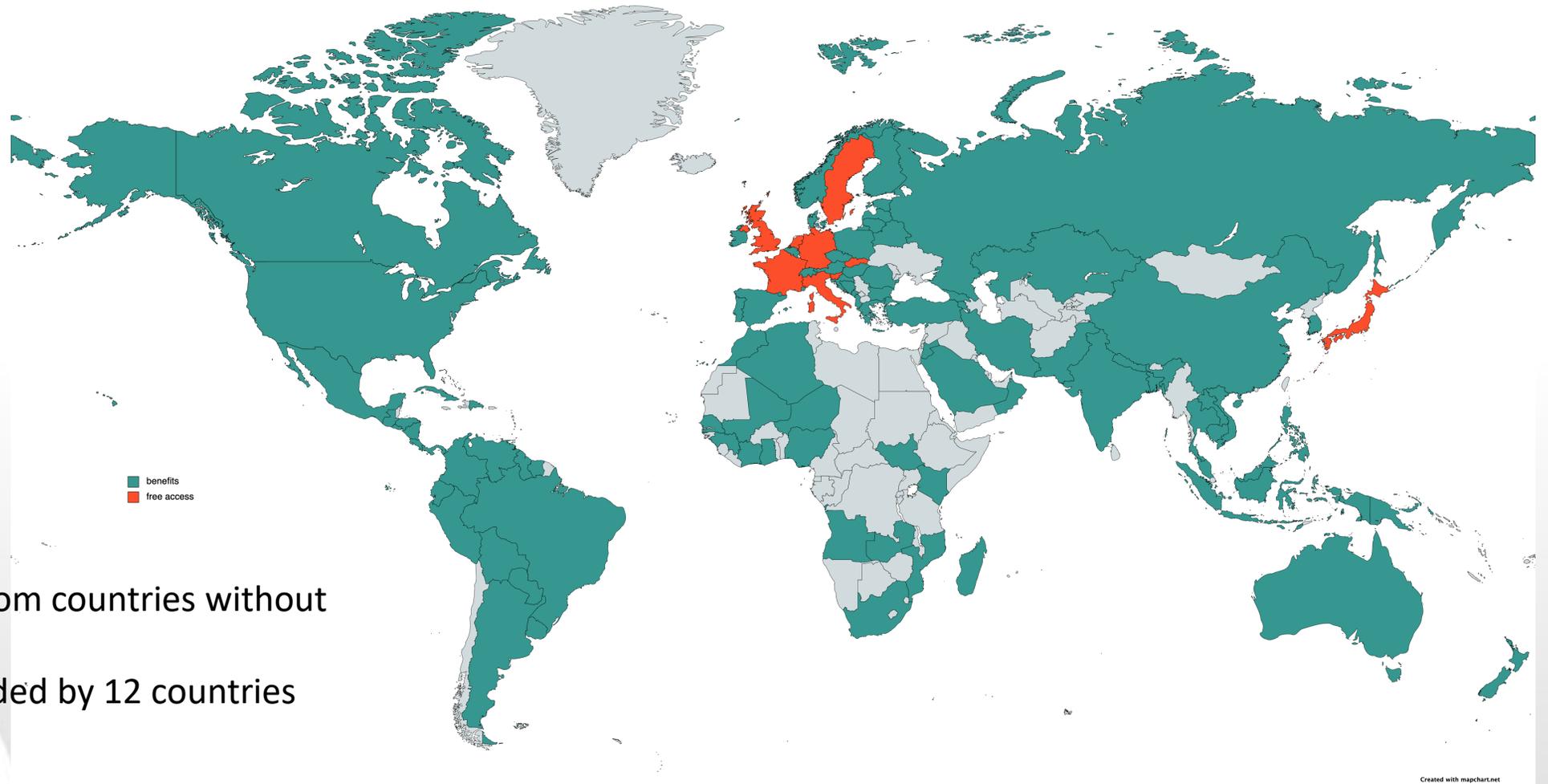
# Pathogen sharing practices

- Sharing is facilitated when pathogen comes from countries without access regulations
- No legal obligation to share genetic resources
- COVID19 vs Zika 2016 sharing

## Introduction to access and benefit-sharing



# Pathogen sharing during the COVID19 pandemic

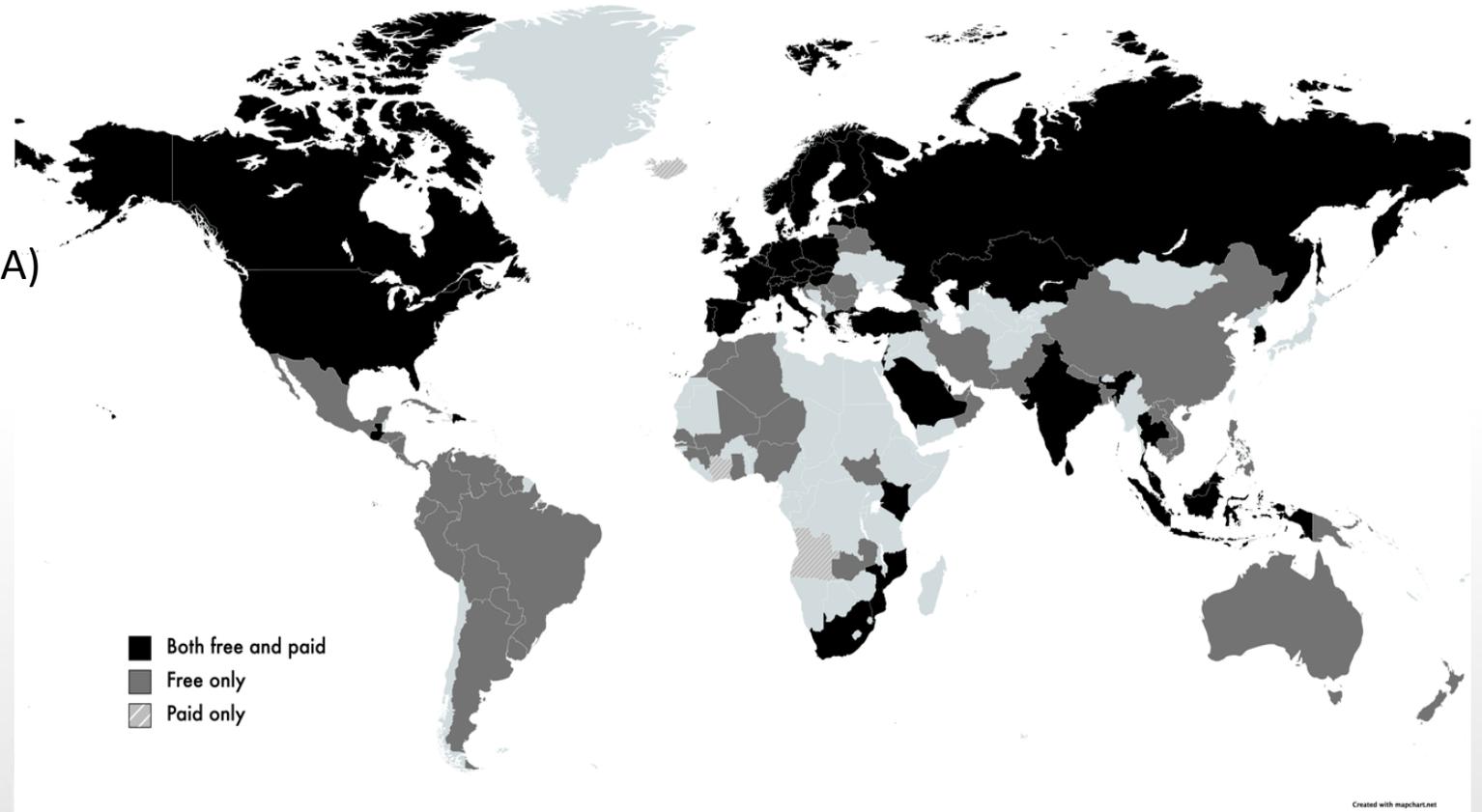


- All SARS-CoV-2 from countries without access legislation
- PGR **access** provided by 12 countries **benefitted** 97

Sett et al. *The Lancet Microbe*. Nov.2021. [https://www.thelancet.com/journals/lanmic/article/PIIS2666-5247\(21\)00211-1/fulltext](https://www.thelancet.com/journals/lanmic/article/PIIS2666-5247(21)00211-1/fulltext)

# Benefits received from pathogen sharing

- 2300 products distributed
- 78% public sector
  - 72% provided free of charge (TNA)
  - 20% allowance lifted during pandemic
  - 50% of TNAs to LMICs
- 22% private sector → all paid for
- Benefit-sharing occurred without access regulation!



Sett et al. *The Lancet Microbe*. Nov.2021. [https://www.thelancet.com/journals/lanmic/article/PIIS2666-5247\(21\)00211-1/fulltext](https://www.thelancet.com/journals/lanmic/article/PIIS2666-5247(21)00211-1/fulltext)

# A tale of two patents

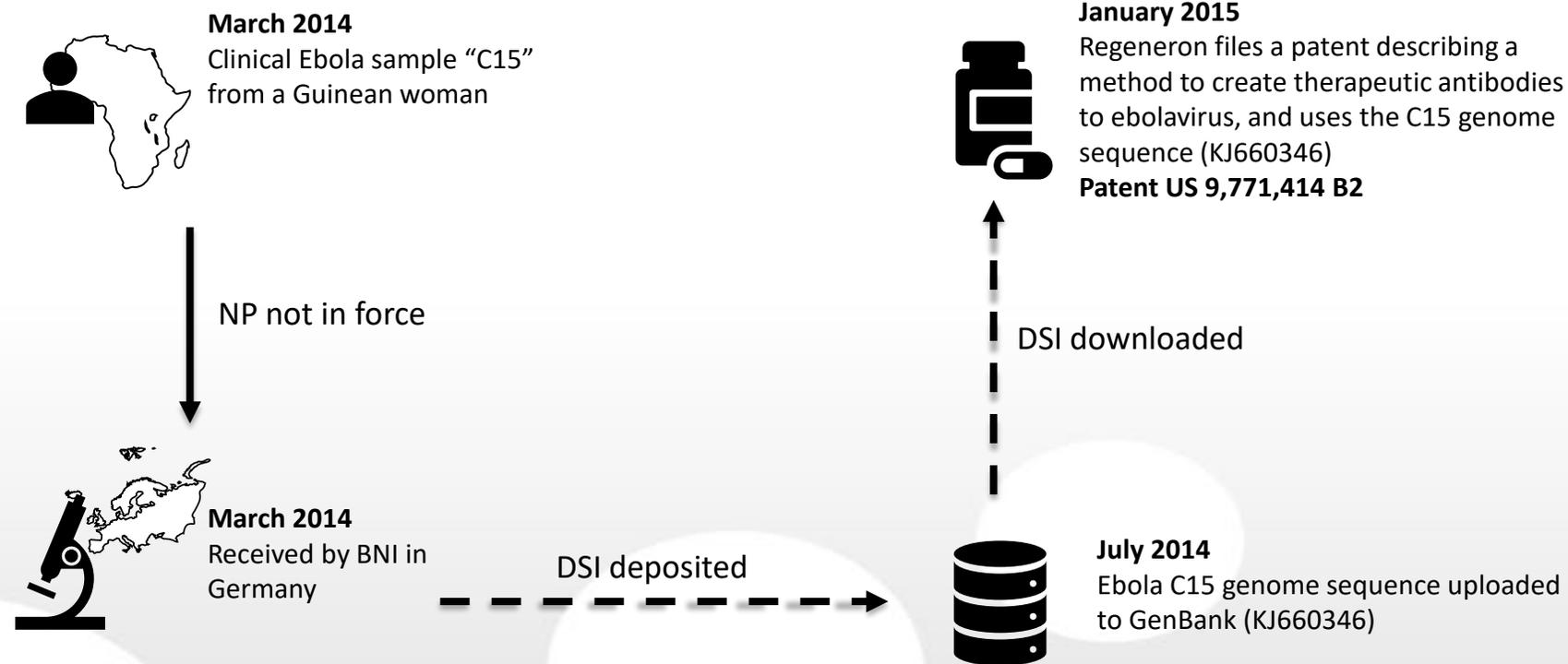
Case studies exploring DSI use in the Regeneron and Moderna patents



Andrew Lee Hufton



# Regeneron Pharmaceuticals and the Ebola vaccine *a tale of biopiracy accusations and the search for facts*



Hammond, E. *Third World Network* [https://twm.my/title2/briefing\\_papers/No99.pdf](https://twm.my/title2/briefing_papers/No99.pdf)

Baize et al. *New England Journal of Medicine* <https://doi.org/10.1056/NEJMoa1404505>

# What makes these sequences so special?

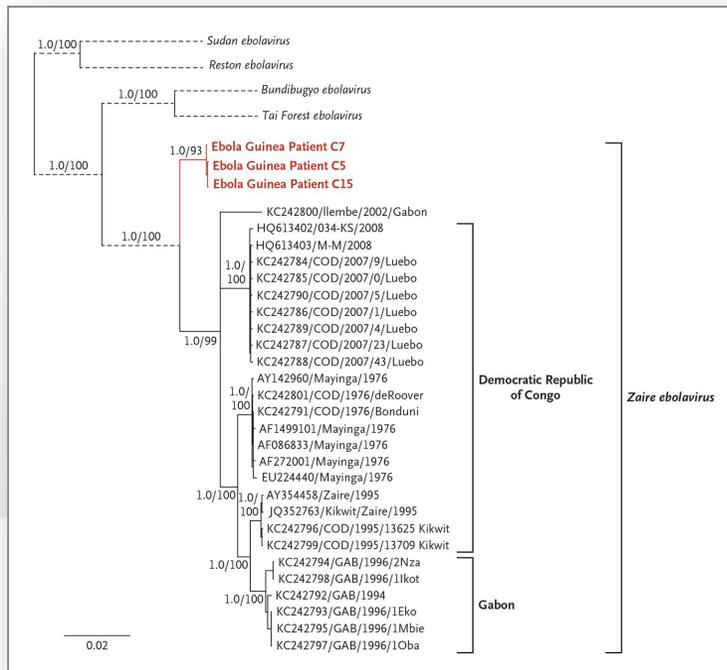
## *...timing*

- By the end of 2014 → 268 sequences
- Patent does not claim novelty of the sequence
- Researchers had access to many nearly identical sequences from different source countries and sequencing centers

ID	Origin	Sequenced in
KP271018.1	DR Congo	UCSF, USA
KP260799.1	Mali	NIAID, USA
KM034562.1	Sierra Leone	Broad Institute, USA
KM655246.1	Zaire	USAMRIID, USA
KJ660346.2	Guinea	Nocht, Germany
KC242784.1	DR Congo	CDC, USA
...	...	...

# Researchers needed large sets of DSI to understand Ebola evolution and epidemiology

## Emergence of Zaire Ebola Virus Disease in Guinea

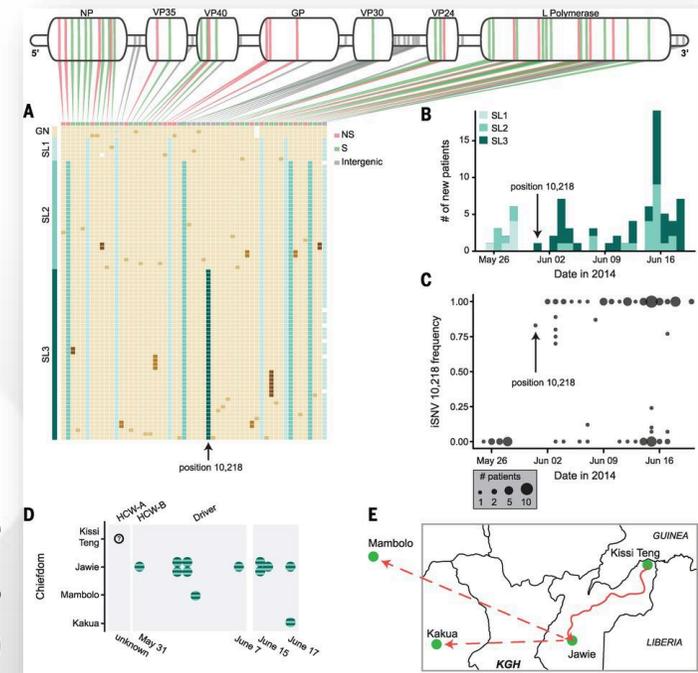


Baize et al. NEMJ  
Releases KJ660346.2  
(July 2014)

Gire et al. Science  
Releases 99 Genomes  
(August 2014)

<https://doi.org/10.1056/NEJMoa1404505>

## Genomic surveillance elucidates Ebola virus origin and transmission during the 2014 outbreak



<https://doi.org/10.1126/science.1259657>

# Moderna betacoronavirus mRNA vaccine

- Filed in Feb 2020
- Describes a general method for generating an mRNA vaccine for a respiratory virus
- Re-submission of old and new sequences (96)
- Does not mention any SARS-CoV-2 sequences



US010702600B1

(12) **United States Patent**  
**Ciaramella et al.**

(10) **Patent No.:** **US 10,702,600 B1**  
(45) **Date of Patent:** **Jul. 7, 2020**

(54) **BETACORONAVIRUS MRNA VACCINE**

(58) **Field of Classification Search**

(71) Applicant: **ModernaTX, Inc.**, Cambridge, MA (US)

None  
See application file for complete search history.

(72) Inventors: **Giuseppe Ciaramella**, Sudbury, MA (US); **Sunny Himansu**, Winchester, MA (US)

(56) **References Cited**

U.S. PATENT DOCUMENTS

(73) Assignee: **ModernaTX, Inc.**, Cambridge, MA (US)

(\* ) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **16/805,587**

(22) Filed: **Feb. 28, 2020**

**Related U.S. Application Data**

(63) Continuation of application No. 16/368,270, filed on Mar. 28, 2019, which is a continuation of application No. 16/040,981, filed on Jul. 20, 2018, now Pat. No. 10,272,150, which is a continuation of application No. 15/674,599, filed on Aug. 11, 2017, now Pat. No. 10,064,934, which is a continuation of application No. PCT/US2016/058327, filed on Oct. 21, 2016.

3,906,092 A	9/1975	Hilleman et al.
4,790,987 A	12/1988	Compans et al.
5,169,628 A	12/1992	Wathen
5,427,782 A	6/1995	Compans et al.
6,225,091 B1	5/2001	Klein et al.
6,500,419 B1	12/2002	Hone et al.
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7,208,161 B1	4/2007	Murphy et al.
7,449,324 B2	11/2008	Fouchier et al.
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8,754,062 B2	6/2014	De Fougères et al.
8,822,663 B2	9/2014	Schrum et al.
8,841,433 B2	9/2014	Fouchier et al.
8,889,146 B2	11/2014	Blais et al.
8,927,206 B2	1/2015	De Jong et al.
8,999,380 B2	4/2015	Bancel et al.
9,192,661 B2	11/2015	Jain et al.

**Patent US 10,702,600 B1**



# Sequence used in the Moderna vaccine

- The sequence used in Moderna's SARS-CoV-2 vaccine was originally treated as a proprietary secret
- It was ultimately disclosed in a 2021 international patent filing: WO2021159040A3

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)  
 (19) World Intellectual Property Organization  
 International Bureau  
 (43) International Publication Date  
 12 August 2021 (12.08.2021) WIPO | PCT

(10) International Publication Number  
**WO 2021/159040 A3**

(51) International Patent Classification:  
*A61K 39/12* (2006.01) *A61P 11/00* (2006.01)  
*A61K 39/215* (2006.01) *A61P 31/14* (2006.01)

(21) International Application Number:  
 PCT/US2021/016979

(22) International Filing Date:  
 06 February 2021 (06.02.2021)

(25) Filing Language:  
 English

(26) Publication Language:  
 English

(30) Priority Data:  
 62/971,825 07 February 2020 (07.02.2020) US  
 63/016,175 27 April 2020 (27.04.2020) US  
 63/044,330 25 June 2020 (25.06.2020) US  
 63/063,137 07 August 2020 (07.08.2020) US

(71) Applicant: MODERNATX, INC. [US/US]; 200 Technology Square, Cambridge, MA 02139 (US).

(72) Inventor: STEWART-JONES, Guillaume; 200 Technology Square, Cambridge, MA 02139 (US).

(74) Agent: LOCKHART, Helen C. et al.; Wolf, Greenfield & Sacks, P.C., 600 Atlantic Avenue, Boston, MA 02210-2206 (US).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, IT, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, WS, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

(54) Title: SARS-COV-2 MRNA DOMAIN VACCINES

Full Spike Protein  
 Subunit Antigens include: Subunit 1(S1)-TM, Soluble S1, Subunit 2(S2)-TM, Soluble S2

**FIG. 1**

(57) Abstract: The disclosure relates to coronavirus ribonucleic acid (RNA) vaccines as well as methods of using the vaccines and compositions comprising the vaccines. The RNA vaccines encode domains and subunits of coronavirus.

WO 2021/159040 A3

# Sequence used in the Moderna vaccine

- The sequence used in Moderna's SARS-CoV-2 vaccine was originally treated as a proprietary secret
- It was ultimately disclosed in a 2021 international patent filing: WO2021159040A3
- The sequence used in the Moderna vaccine is only about 70% identical to natural SARS-CoV-2 sequences

```
>Severe acute respiratory syndrome coronavirus 2 isolate SARS-CoV-2/human/USA/CA-
CDPH-2000014286/2020, complete genome
Sequence ID: OK653344.1 Length: 29872
Range 1: 21557 to 25377
```

```
Score:1496 bits(1658), Expect:0.0,
Identities:2629/3825(69%), Gaps:8/3825(0%), Strand: Plus/Plus
```

```
Query 55 ACCATGTTTCGTGTTCTGTTGCTGCTGCCCTGGTGAGCAGCCAGTGCCTGAACCTGACC 114
      ||| ||||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| |||
Sbjct 21557 ACAATGTTTGTGTTTTCTGTTTTATTGCCACTAGTCTCTAGTCAGTGTGTTAATCTTACA 21616
```

A portion of a BLAST hit between the vaccine sequence and a natural SARS-CoV-2 sequence

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)  
 (19) World Intellectual Property Organization  
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 (43) International Publication Date 12 August 2021 (12.08.2021) WIPO | PCT  
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(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

(54) Title: SARS-COV-2 MRNA DOMAIN VACCINES

FIG. 1

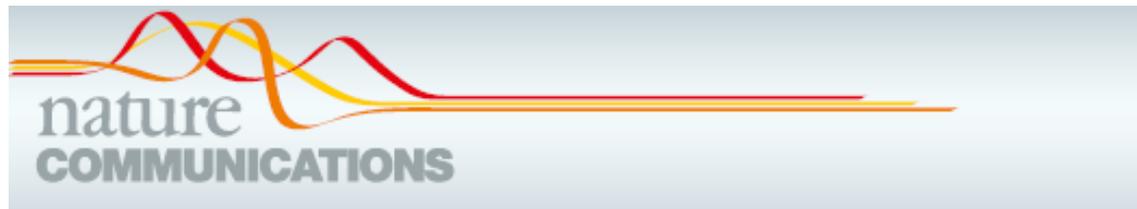
(57) Abstract: The disclosure relates to coronavirus ribonucleic acid (RNA) vaccines as well as methods of using the vaccines and compositions comprising the vaccines. The RNA vaccines encode domains and subunits of coronavirus.

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[Continued on next page]

# Does DSI fit into existing ABS systems?

- DSI regulation under the EU ABS regulation and CBD/NP
- Trying to regulate individual sequences deliberately ignores the reality of how DSI research is conducted
- Tracking and tracing individual may not fairly reward all of the contributors of data to the public system - incentivizes jurisdiction shopping
- An effective benefit-sharing system for DSI needs to recognize the value of the entire sequence dataset and reward rapid & open sharing



## COMMENT

<https://doi.org/10.1038/s41467-022-28594-0>

OPEN

# Multilateral benefit-sharing from digital sequence information will support both science and biodiversity conservation

<https://www.nature.com/articles/s41467-022-28594-0>

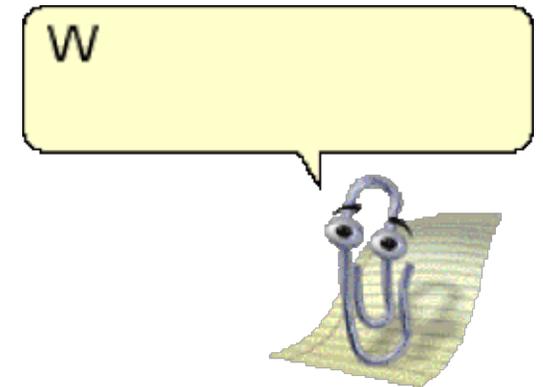
41 authors from 17 countries

Amber Hartman Scholz <sup>1✉</sup>, Jens Freitag<sup>2</sup>, Christopher H. C. Lyal <sup>3</sup>, Rodrigo Sara<sup>1,4</sup>, Martha Lucia Cepeda<sup>5</sup>, Ibon Cancio <sup>6</sup>, Scarlett Sett<sup>1</sup>, Andrew Lee Hufton <sup>1</sup>, Yemisrach Abebaw<sup>7</sup>, Kailash Bansal<sup>8</sup>, Halima Benbouza <sup>9</sup>, Hamadi Iddi Boga<sup>10</sup>, Sylvain Brisse<sup>11</sup>, Michael W. Bruford<sup>12</sup>, Hayley Clissold <sup>13</sup>, Guy Cochrane<sup>14</sup>, Jonathan A. Coddington<sup>15</sup>, Anne-Caroline Deletoille <sup>11</sup>, Felipe García-Cardona<sup>16</sup>, Michelle Hamer<sup>17</sup>, Raquel Hurtado-Ortiz <sup>11</sup>, Douglas W. Miano<sup>18</sup>, David Nicholson <sup>13</sup>, Guilherme Oliveira <sup>19</sup>, Carlos Ospina Bravo<sup>20</sup>, Fabian Rohden <sup>21</sup>, Ole Seberg <sup>22</sup>, Gernot Segelbacher <sup>23</sup>, Yogesh Shouche<sup>24</sup>, Alejandra Sierra<sup>25</sup>, Ilene Karsch-Mizrachi<sup>26</sup>, Jessica da Silva<sup>17,27</sup>, Desiree M. Hautea<sup>28</sup>, Manuela da Silva <sup>29</sup>, Mutsuaki Suzuki <sup>30</sup>, Kassahun Tesfaye<sup>7,31</sup>, Christian Keambou Tiambo <sup>32</sup>, Krystal A. Tolley <sup>17,27</sup>, Rajeev Varshney <sup>33</sup>, María Mercedes Zambrano <sup>34</sup> & Jörg Overmann <sup>1,35</sup>

Open access to sequence data is a cornerstone of biology and biodiversity research, but has created tension under the United Nations Convention on Biological Diversity (CBD). Policy decisions could compromise research and development, unless a practical multilateral solution is implemented.



# Thank you for your attention



## Acknowledgments

Dr. Amber Hartman Scholz (lead of the Science Policy team)

Dr. Andrew Hufton (WilDSI 2.0 project)



H2020 grant agreement 871029







# Sugarcane mosaic virus SCMV

PV-1207

<b>Name:</b>	<i>Sugarcane mosaic virus</i>
<b>Abbreviation:</b>	SCMV
<b>Family:</b>	<i>Potyviridae</i>
<b>Genus:</b>	<i>Potyvirus</i>
<b>Reference(s):</b>	<a href="#">15688</a>
<b>Virus isolate:</b>	
<b>DSMZ No.:</b>	PV-1207
<b>Original Host Plant:</b>	<i>Zea mays</i> , Maize
<b>Geographic Origin:</b>	Ethiopia → <b>Geographic scope</b>
<b>Date of Sampling:</b>	in/before 2016 → <b>Temporal scope</b>
<b>Nagoya Protocol Restrictions:</b>	Documentation related to the Convention on Biological Diversity and the Nagoya Protocol. Users must download, read, and adhere to the terms listed in the document(s) listed here. Users are legally required to maintain records of these document(s) for 20 years after the last use of the resource. <a href="#">File Download</a>
<b>History:</b>	DSMZ < Demsachew Guadie Tseganeh, Addis Ababa University, Ethiopia
<b>Supplied as:</b>	- Virus inoculum - Nucleic acid extracts from virus-infected plants on request

