Implementation Pathway: TRUST ISO 16363/ISO 16919 intersections

Dr David Giaretta
Director of PTAB
david@giaretta.org
http://www.iso16363.org

TRUST

Transparency	**To be transparent about specific repository services and data holdings that are verifiable by publicly accessible evidence.**
Responsibility	**To be responsible for ensuring the authenticity and integrity of data holdings and for the reliability and persistence of its service.**
User Focus	**To ensure that the data management norms and expectations of target user communities are met.**
Sustainability	**To sustain services and preserve data holdings for the long-term.**
Technology	**To provide infrastructure and capabilities to support secure, persistent, and reliable services.**

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TRUST, but VERIFY

- A Russian proverb used by President Reagan when talking about nuclear disarmament.

- *While "trust, but verify," at times, can be an essential approach, often it's detrimental. Effective trust-building and leadership practices require knowing when and why to use it.*
- *When the outcome is essential and matters more than the relationship, use "trust, but verify." When the relationship matters more than any single outcome, don't use it.* https://www.psychologytoday.com/gb/blog/trust-the-new-workplace-currency/201507/the-problem-trust-verify-approach

The Devil is in the Details

It must be clear what the repository is claiming to do (following OAIS):

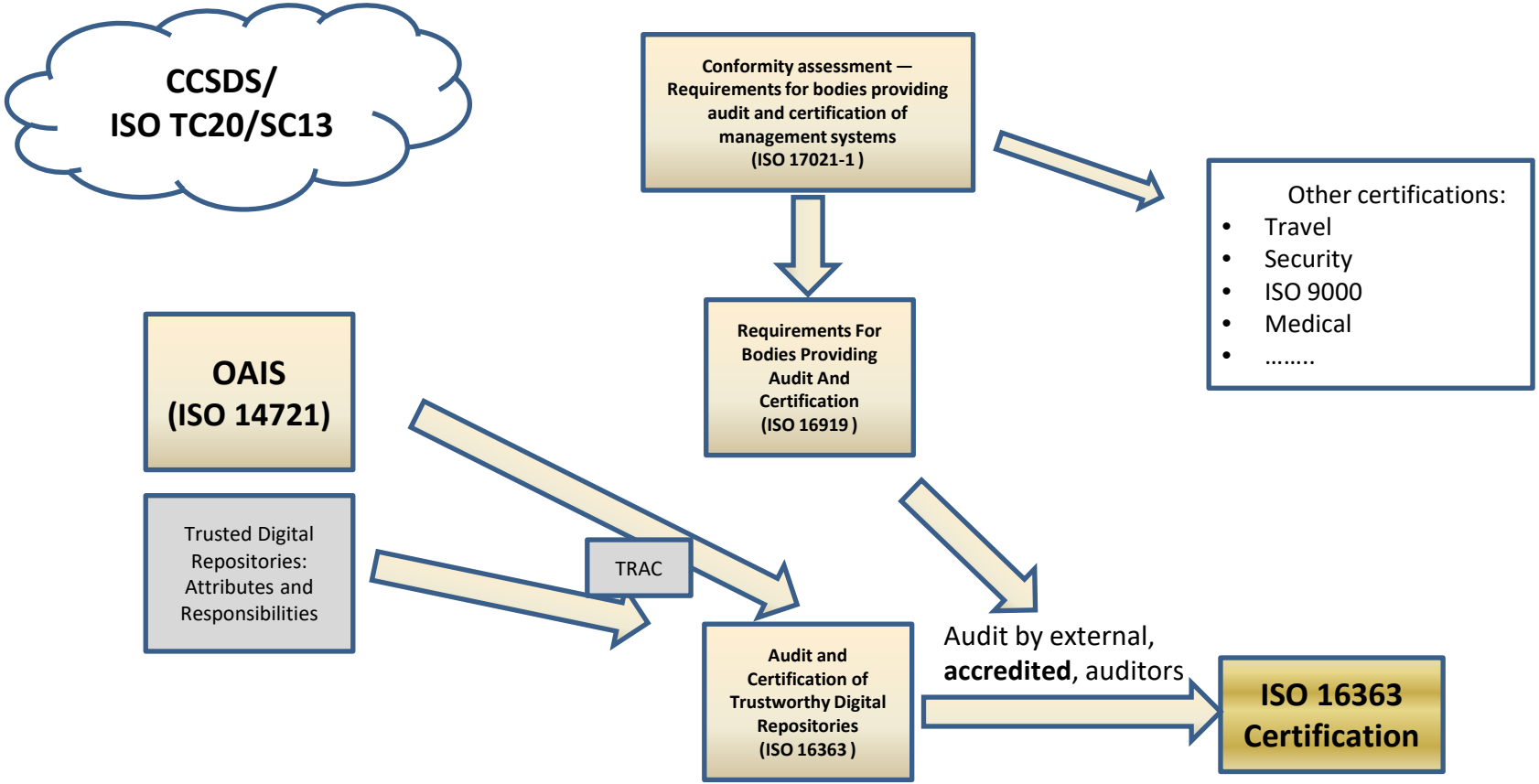
- Who is the repository guaranteeing will be able to understand/use what is being preserved? Clearly that cannot be everyone! What is its Designated Community?
  - Are such people able to understand/use the information? **Testable**.
- Usability – clarified by being specific about “Preservation Objectives”
  - What should the Designated Community be able to do? **Testable**
- Authenticity
  - What evidence can be provided to support claims of Authenticity? **Checkable**
- Integrity
  - Fixity if bits not changed
    - Fixity Information. **Testable**
  - Transformation Information Properties if the bits are changed
    - **Testable**

- Other things are subjective and depend on the judgement of the auditors
  - Who does the audits?
  - How can we be sure they are done consistently?

Why ISO?

- ISO audits are used across the World and in vast numbers of areas on which our lives depend.
- The ISO process ensures international consistency of certification and their international recognition
- Everyone at every level is tested/evaluated every year

Relationship between standards



ISO 17021

- …specifies **requirements for bodies providing audit and certification of management systems**.
- .. gives **generic requirements** for such bodies performing audit and certification in …..
- **Observance of these requirements is intended to ensure that certification bodies operate management system certification in a competent, consistent and impartial manner**, thereby **facilitating the recognition of such bodies and the acceptance of their certifications on a national and international basis**.
- ….. serves as a foundation for **facilitating the recognition of management system certification in the interests of international trade**.
- **Certification of a management system provides independent demonstration that the management system of the organization**:

a) conforms to specified requirements;

b) is capable of consistently achieving its stated policy and objectives;

c) is effectively implemented.

Conformity assessment, such as the certification of a management system, thereby **provides value to the organization, its customers and interested parties**.

ISO 17021 Principles for inspiring confidence include

- impartiality;
- competence;
- responsibility;
- openness;
- confidentiality;
- responsiveness to complaints;
- risk-based approach.

Auditor behaviour

a) ethical, i.e. fair, truthful, sincere, honest and discreet;
b) open-minded, i.e. willing to consider alternative ideas or points of view;
c) diplomatic, i.e. tactful in dealing with people;
d) collaborative, i.e. effectively interacting with others;
e) observant, i.e. actively aware of physical surroundings and activities;
f) perceptive, i.e. instinctively aware of and able to understand situations;
g) versatile, i.e. adjusts readily to different situations;
h) tenacious, i.e. persistent and focused on achieving objectives;
i) decisive, i.e. reaches timely conclusions based on logical reasoning and analysis;
j) self-reliant, i.e. acts and functions independently;
k) professional, i.e. exhibiting a courteous, conscientious and generally business-like demeanour in
the workplace;
l) morally courageous, i.e. willing to act responsibly and ethically even though these actions may not
always be popular and may sometimes result in disagreement or confrontation;
m) organized, i.e. exhibiting effective time management, prioritization, planning, and efficiency.

ISO Standards – who can audit?

METRIC

- OAIS – ISO 14721
- ISO 16363
- ISO 27001
- ISO 15489

STANDARD FOR REQUIREMENTS FOR AUDITORS

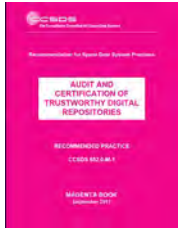
- None
- ISO 16919
- ISO 19896
- None

ISO 16363

Audit and Certification of Trustworthy Digital Repositories

Designed for audit – self audit and independent auditors

- Hierarchy of metrics – to make the auditor look at more and more specific details when required
- Metrics and their structure:
  - Statement of requirement
  - Supporting text
  - Examples of Ways the Repository can Demonstrate it is Meeting this Requirement
  - Discussion
- NUMBER of metrics at each level



Metrics	Top level X	Metric X.X	Sub-metric X.X.X	Sub-sub metric X.X.X.X	Sub-sub-sub metric X.X.X.X.X
Organisational Infrastructure	**1**	**6**	**21**	**31**	**31**
Digital Object Management	**1**	**7**	**36**	**62**	**67**
Infrastructure and Security Risk Management	**1**	**3**	**9**	**16**	**27**
TOTAL	**3**	**16**	**66**	**109**	**125**

Examples of metrics

1 ORGANIZATIONAL INFRASTRUCTURE

1.1 GOVERNANCE AND ORGANIZATIONAL VIABILITY

1.1.1 The repository shall have a mission statement that reflects a commitment to the preservation of, long term retention of, management of, and access to digital information.

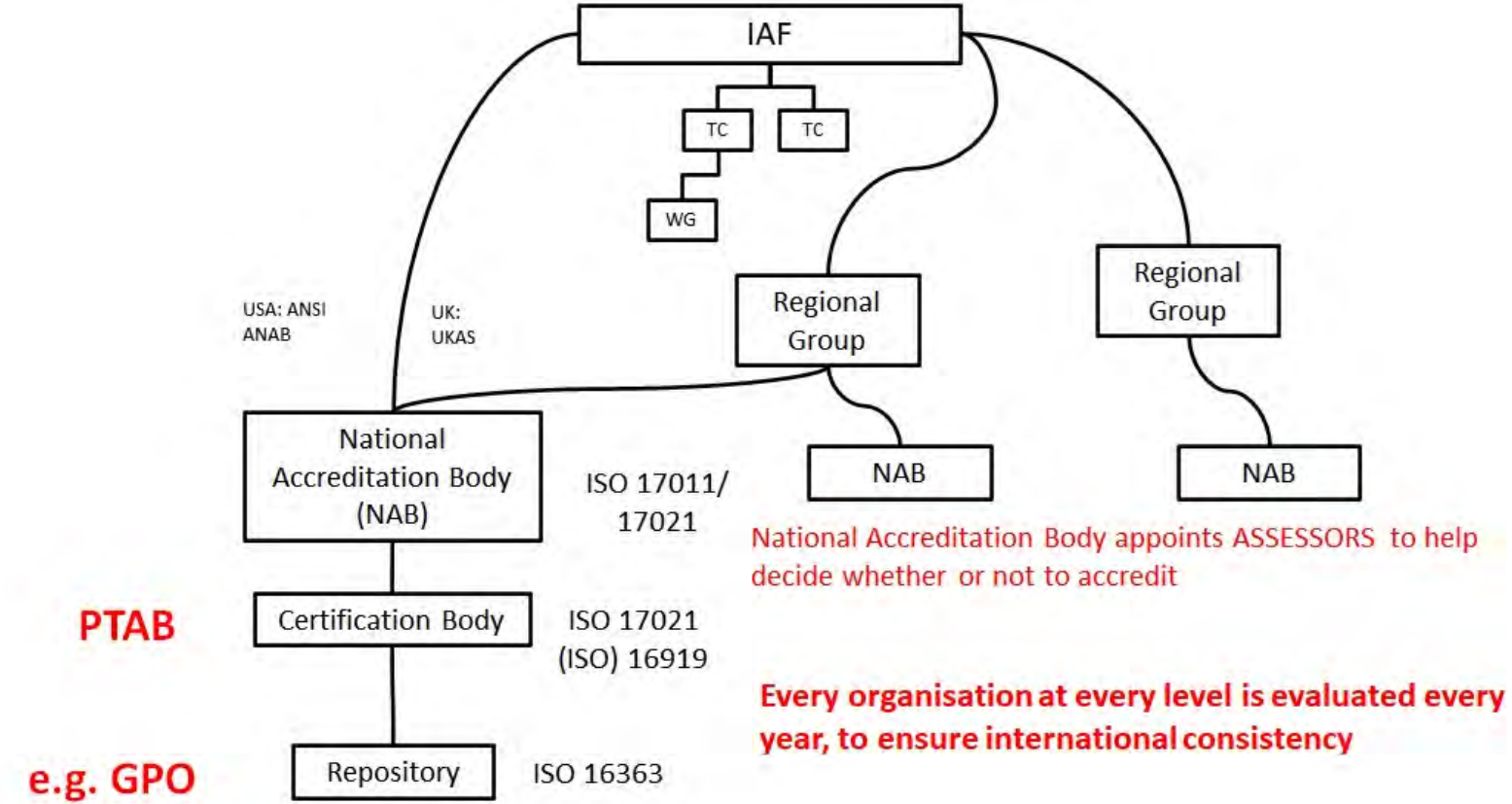
1.1.2 The repository shall have a Preservation Strategic Plan that defines the approach the repository will take in the long-term support of its mission.

1.1.2.1 The repository shall have an appropriate succession plan, contingency plans, and/or escrow arrangements in place in case the repository ceases to operate or the governing or funding institution substantially changes its scope.

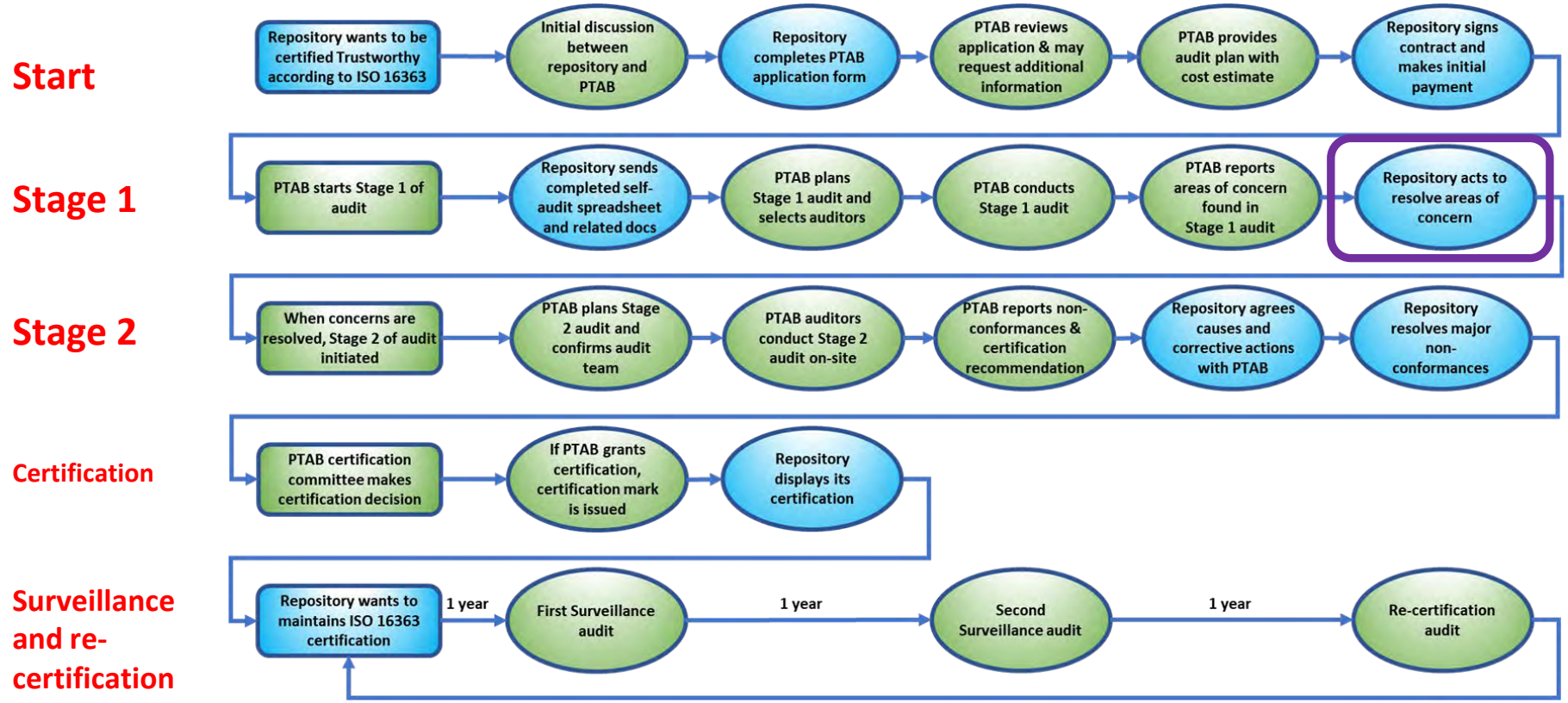
1.1.2.2 The repository shall monitor its organizational environment to determine when to execute its succession plan, contingency plans, and/or escrow arrangements.

1.1.3 The repository shall have a Collection Policy or other document that specifies the type of information it will preserve, retain, manage, and provide access to.

ISO Accreditation and Certification



PTAB Process following ISO 17021



TRUST PRINCIPLES ARE A START

- **Very easy to claim that one’s repository follows the TRUST principles**

BUT

- **the details matter**
- **the auditors matter**
- **the process matters**

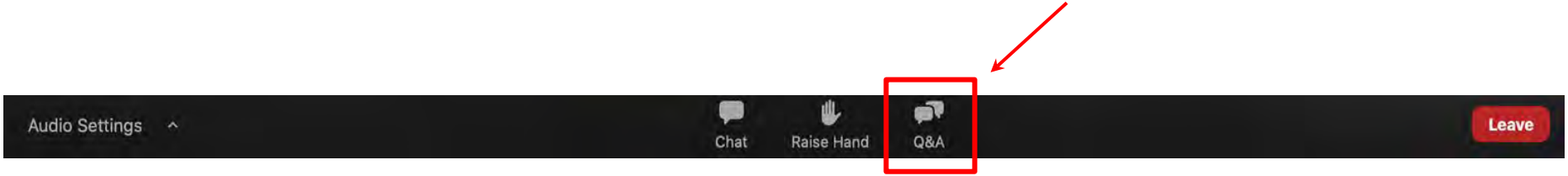
Trust but Verify - because our digitally encoded intellectual capital is important

References

- **ISO/IEC 17021-1:2015** Conformity assessment -- Requirements for bodies providing audit and certification of management systems -- Part 1: Requirements, available from http://www.iso.ch
- Audit and Certification of Trustworthy Digital Repositories. Magenta Book. Issue 1. September 2011., available from https://public.ccsds.org/Pubs/652x0m1.pdf also known as **ISO 16363:2012**
- Reference Model for an Open Archival Information System (OAIS). Magenta Book. Issue 2. June 2012, available from https://public.ccsds.org/Pubs/650x0m2.pdf also known as **ISO 14721:2012**,
- Requirements for Bodies Providing Audit and Certification of Candidate Trustworthy Digital Repositories. Magenta Book. Issue 2. March 2014, available from https://public.ccsds.org/Pubs/652x1m2.pdf also known as **ISO 16919:2014**

Questions & Answers

- Please use the Q&A option to ask questions of the presenter(s). Questions will be addressed at the end of each session when possible, and also at the end of the Symposium.
- The Q&A option can be found at the bottom of your Zoom screen:



TRUST: Transparency, Responsibility, User focus, Sustainability, Technology

RDA Research Data Alliance | World Data System

RDC DRC Research Data Canada – Données de Recherche Canada

BREAK


TRUST
Transparency
Responsibility
User focus
Sustainability
01010
10101
01010
Technology

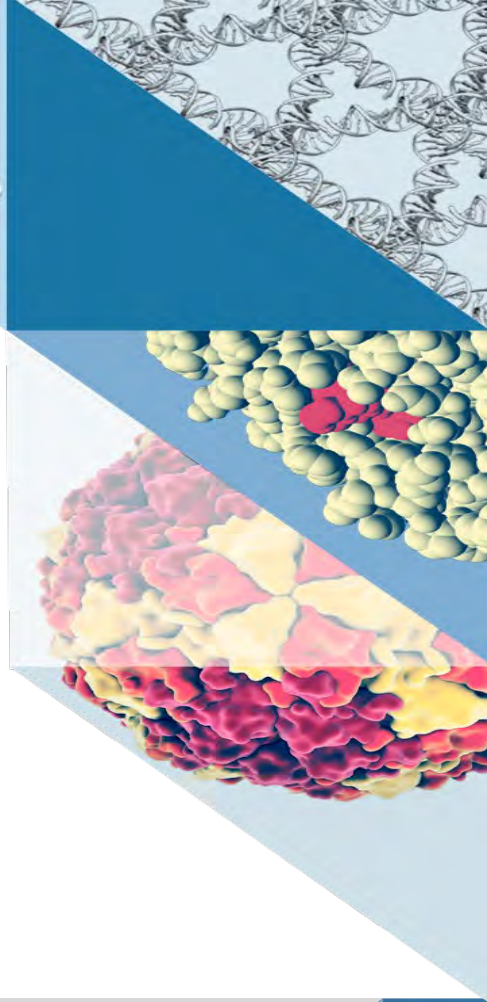

RDA
RESEARCH DATA ALLIANCE


WORLD
DATA SYSTEM


RDC
DRC
Research Data Canada – Données de Recherche Canada

RCSB PDB
PROTEIN DATA BANK

Protein Data Bank
A Community Archival Data Repository Example



RDA RESEARCH DATA ALLIANCE

WORLD DATA SYSTEM

RDC DRC

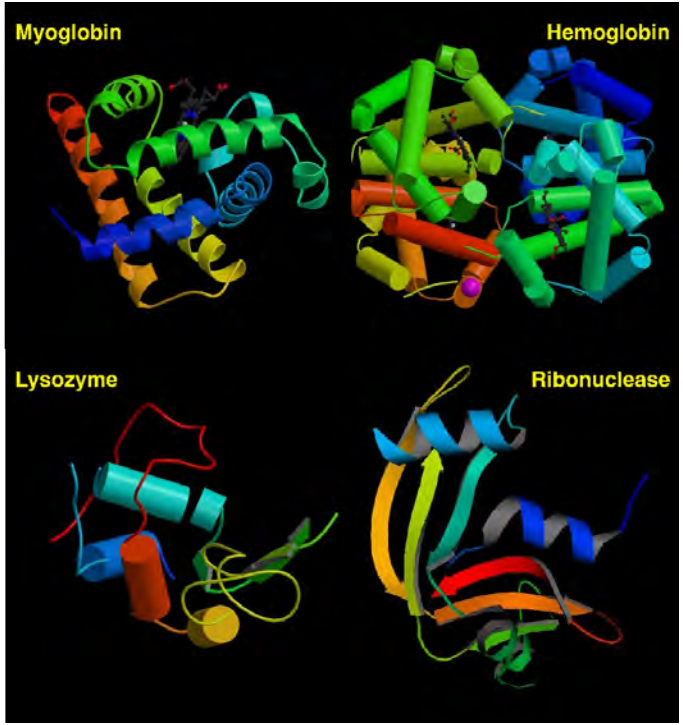
John Westbrook RCSB PDB

Outline

- Brief overview of the PDB resources and services
- PDB support of the TRUST principles
- Some challenges for repository maintainers

Protein Data Bank Established 1971

- PDB 1st Open Access digital data resource in all of biology
- Founded with 7 X-ray crystal structures of proteins
- Single global **archive** for protein and DNA/RNA experimental structures
- Today, Open Access to >165,000 structures
- wwPDB collaboration US (RCSB PDB), EU (PDBe), and Japan (PDBJ), and BMRB (EMDB to join early 2020)



Structures that Inspired Launch of the PDB

wwPDB Partnership Established 2003

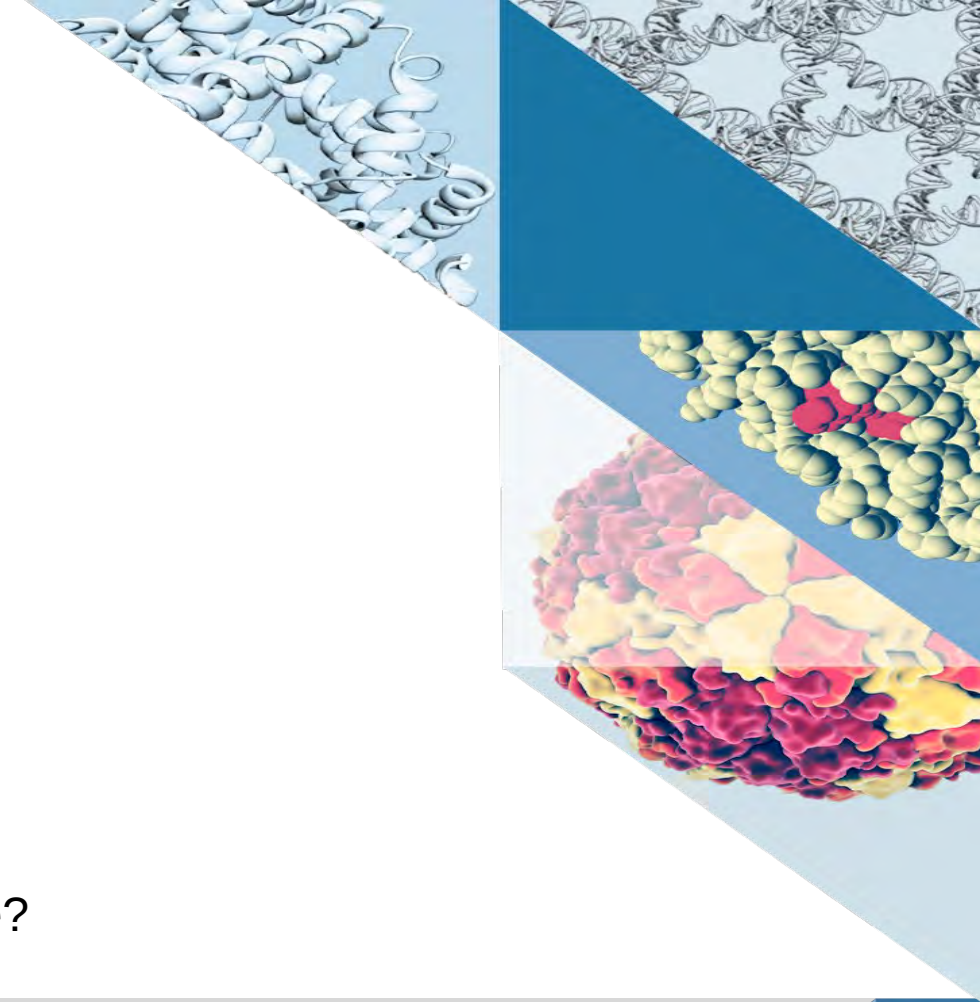
- RCSB PDB, PDBe, and PDBj (all locally funded) manage PDB according to **FAIR**
- Collaborate on Data In

- RCSB PDB is Archive Keeper

- wwPDB governed by Memorandum of Understanding mandating
  - Policies/Procedures
  - No charge for Data Deposition
  - No charge for Data Download
- RCSB PDB, PDBe, and PDBj each provide open access to complementary views of identical PDB Data for Public/Industry Research and Education

FAIR=Findability+**A**ccessibility+**I**nteroperability+**R**eusability

RCSB PDB
PROTEIN DATA BANK



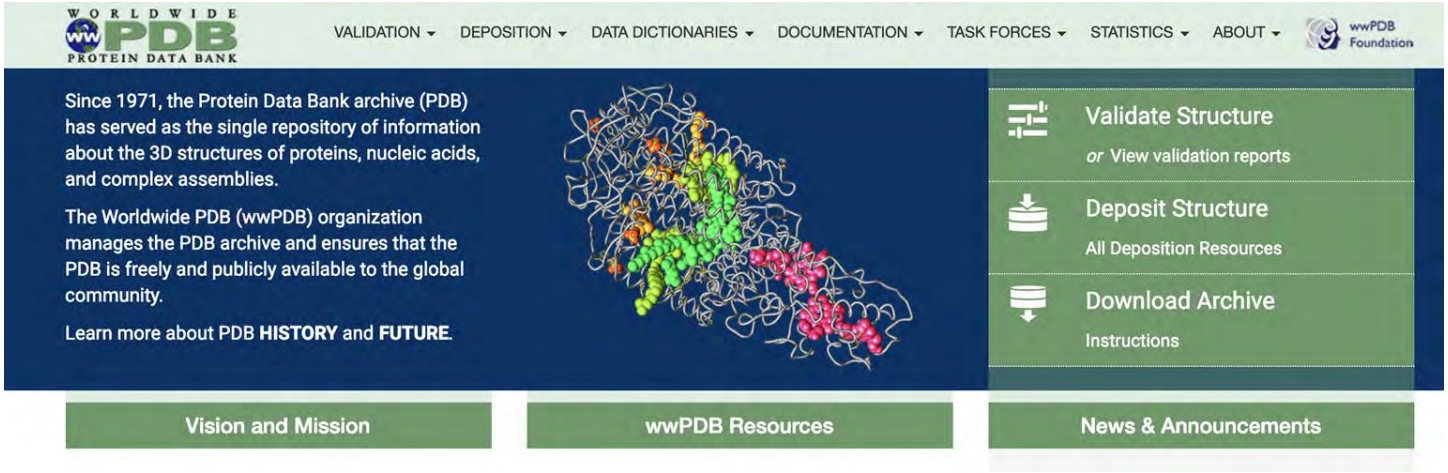
TRUST

Transparency

What do you do?
How do you do it?
Can I get a copy?
Is what you do fit for purpose?

Articulation of Mission and Scope

- wwPDB maintains a single archive of macromolecular structural data that are freely and publicly available to the global community
- wwPDB maintains these organizational details on the wwpdb.org resource portal along with other key project documentation



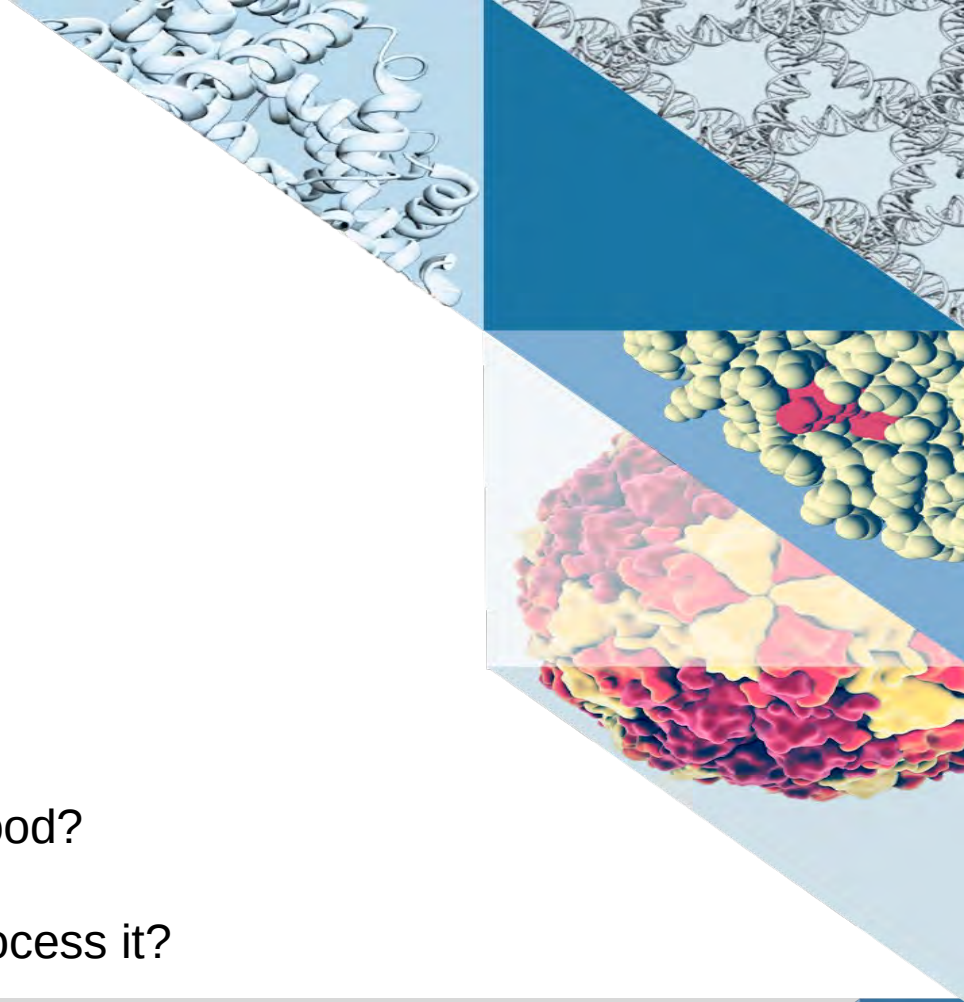
Licenses and Terms of Use

- PDB primary data are free of all copyright restrictions and made fully and freely available for both non-commercial and commercial users
- This PDB license pre-dates contemporary open source licenses
- Some additional conditions on adaptation of data protect authenticity of repository data files
- Compliance issues with primary data are rare
- Other PDB software and educational materials are provided under standard open source licenses (e.g., Apache and Creative Commons)

CoreTrustSeal Certification

- Strong commitment and tradition within our scientific community for support of data and process standards
- Expectations of both our repository contributors and users to adopt and maintain best practices in archiving and data management
- Increasing focus of funders on supporting FAIR data management practices
- Certification documents the resource investment required to responsibly manage the full life cycle of archival data
- Relatively low barrier and modest effort certification process
- Good balance between rigor and certification effort

RCSB PDB
PROTEIN DATA BANK



tRust

Responsibility

What data do you have?
What do you call it?
Who says the data are any good?
How can I find it?
Can my program read and process it?

Data Integrity and Authenticity

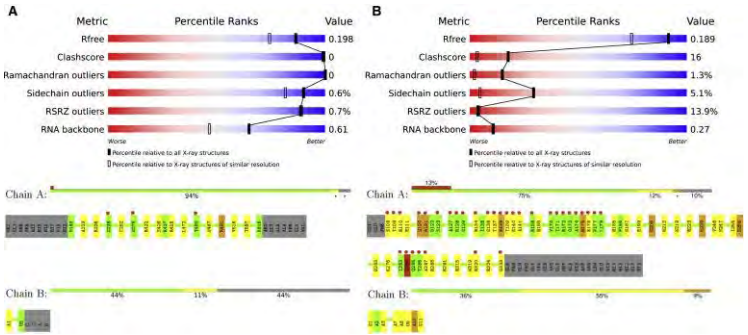
- Community metadata and data standards
- Metadata and data change management policies
- Expert biocuration
- Maintaining consistency through retrospective repository remediation
- ORCID identification for depositors

Data Quality Standards

- All PDB deposition, validation and biocuration tools support and enforce Community data standards
- PDB provides validation reports describing compliance with Community data quality standards
- Validation reports tailored for a range of audiences: depositors, editorial reviewers, and general users
- PDB validation reports required by most scientific journals describing 3D structure determinations

Data Appraisal

- Pre-deposition validation services
- wwPDB OneDep Deposition System
- Expert biocuration
- Data and data diagnostics delivered in well-defined community data formats



Expert Community Guidance

wwPDB Method-specific Community Task Forces

Task Force	Meeting	Chair(s)/Membership	Outcomes
X-ray Validation Task Force	2008 2015	Randy Read (Univ of Cambridge) 17 members	(2011) Structure 19: 1395-1412
NMR Validation Task Force	2009- 2019	Gaetano Montelione (Rutgers) Michael Nilges (Institut Pasteur) 10 members	(2013) Structure 21: 1563-1570
3DEM Validation Task Force	2010	Richard Henderson (MRC-LMB) Andrej Sali (UCSF) 21 members	(2012) Structure 20: 205-214
Small-Angle Scattering Task Force	2011 2014	Jill Trewhella (Univ Sydney) 6 members	(2013) Structure 21: 875-881 (2017) Acta Cryst D73
Hybrid Methods Task Force	2014	Andrej Sali (UCSF), Torsten Schwede (Univ Basel), Jill Trewhella (Univ Sydney) 27 members	(2015) Structure 23: 1156-1167
Ligand Validation Workshop	2015		(2016) *Structure* 24: 502-508
PDBx/mmCIF Working Group	2011 -	Paul Adams (LBL) 13 members	Regular virtual meetings and workshops

Data Discovery, Identification, and Integrated Access

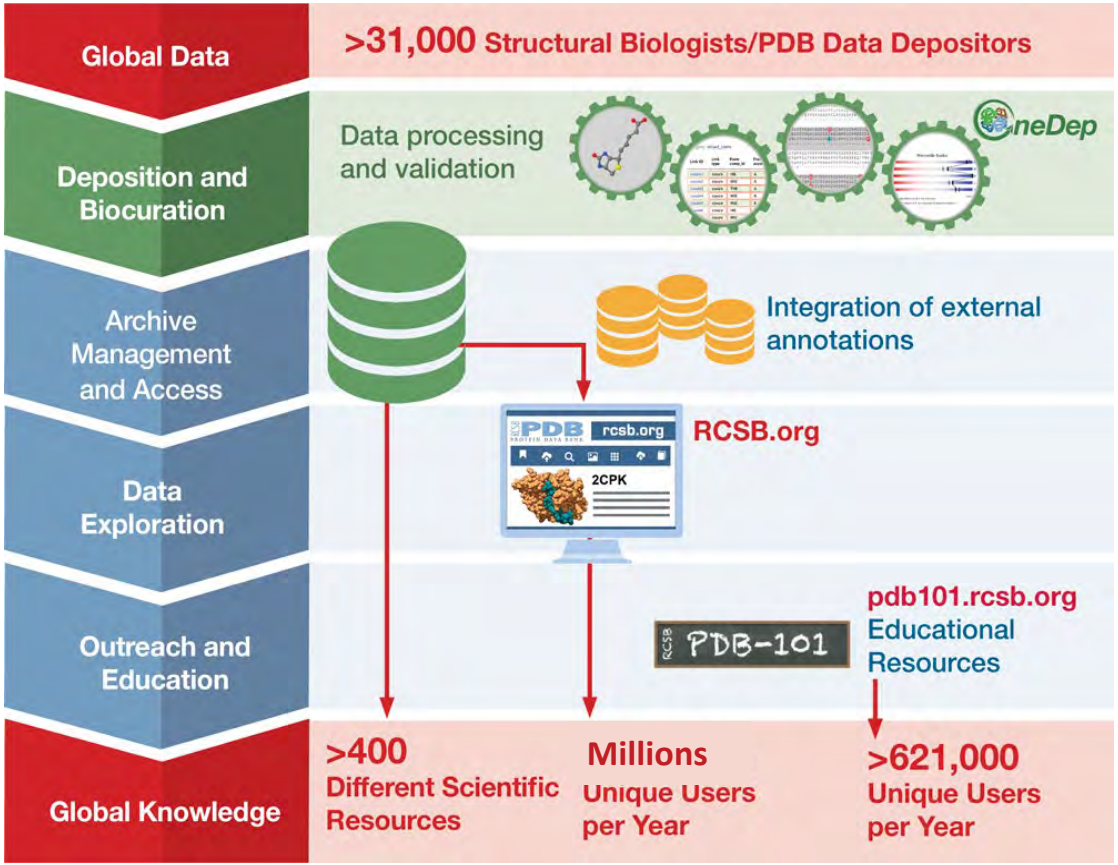
RCSB PDB
PROTEIN DATA BANK

TRUST

User Focus

Who is using your data?
How do you know (not just clicks and downloads)?
Is anything useful being done with your data?
What are you doing to make that easier?

RCSB PDB Services Support Full Data Lifecycle



Burley *et al*. (2019) *Nucleic Acids Research 47,* D464-D474.

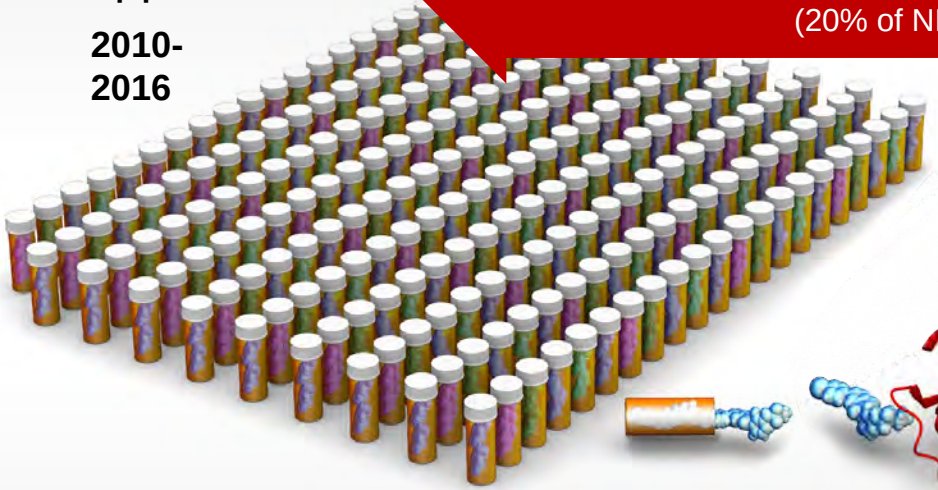
Impact on US FDA New Drug Approvals[1]

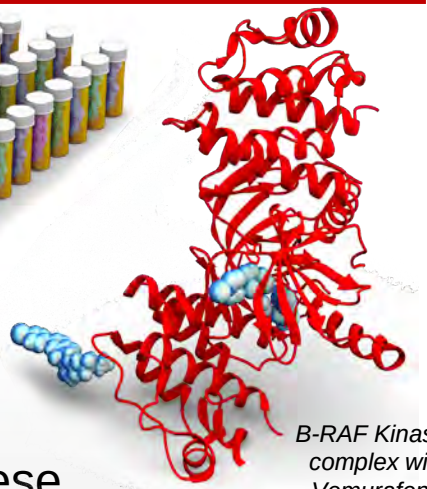
210 NEW DRUGS approved

2010-2016

2000-2016

>$100 BILLION **of NIH funding** contributed to these approvals (20% of NIH Budget)[2]





B-RAF Kinase complex with Vemurafenib

PDB ID 3og7

Bollag *et al.* (2010) *Nature 467*, 596-599

5,914 PDB Structures facilitated

184 of these drug approvals

1. Westbrook & Burley (2019) *Structure 27*, 211-217
2. Galkina Cleary *et al.* (2018) *PNAS 115,* 2329-2334; Value in 2016 US$

Impact on Anti-neoplastic Drug Approvals[1]

79 NEW ANTI-CANCER DRUGS Approved 2010-2018

74 of these new drugs

had a total of **2412** **unique structures in the PDB** explaining target biology and facilitating discovery/development

Structure-guided drug discovery □ >70% of small-molecule drugs

1. Westbrook *et al*. (2020) *Drug Discovery Today* 25, in press

Supporting Reusability and Extensibility

- Data and metadata requirements for deposition
- Content and format extensibility
- Maintaining repository content and format consistency through retrospective biocuration
- Repository metadata and data content documentation (mmcif.wwpdb.org)

Outreach and Educational Resources

PDB-101 Molecule of the Month Browse Learn Global Health Teach SciArt Events More

PDB-101 Molecular explorations through biology and medicine

Search Molecule of the Month articles and more Go

Educational portal of PDB

Celebrating 20 YEARS OF Molecule of the Month

Molecule of the Month By Category By Date By Title

Coronavirus Proteases

Coronavirus proteases are attractive targets for the design of antiviral drugs.

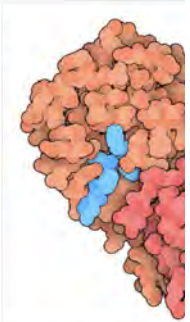
In this world of fast and easy travel, emerging viruses are increasingly becoming a major danger to world health. Coronaviruses are a notable example. Particularly virulent forms have emerged from their natural animal hosts and pose a threat to human communities. In 2003, the SARS virus emerged in China from bat populations, moving to civets and finally to humans. Ten years later, the MERS virus also emerged from bats, transferring in the Middle East to dromedary camels and then to humans. Recently, another coronavirus has emerged in China by way of animals in a live market. Structural biology is helping us understand these dangerous foes, and hopefully will help us develop new ways to fight them.

Coronavirus Code

Coronaviruses contain a genome composed of a long RNA strand—one of the largest of all RNA viruses. This genome acts just like a messenger RNA when it infects a cell, and directs the synthesis of two long polyproteins that include the machinery that the virus needs to replicate new viruses. These proteins include a replication/transcription complex that makes more RNA, several structural proteins that construct new virions, and two proteases. The proteases play essential roles in cutting the polyproteins into all of these functional pieces.

Main Protease

The main protease of coronavirus makes most of these cuts. The one shown here (PDB entry 6lu7) is from the SARS-CoV-2 (2019-nCoV) coronavirus that is currently posing dangers in Wuhan. It is a dimer of two identical subunits that together form two active sites. The protein fold is similar to serine proteases like trypsin, but a cysteine amino acid and a nearby histidine perform the protein-cutting reaction and an extra domain stabilizes the dimer. This structure has a peptide-like inhibitor bound in the active site.

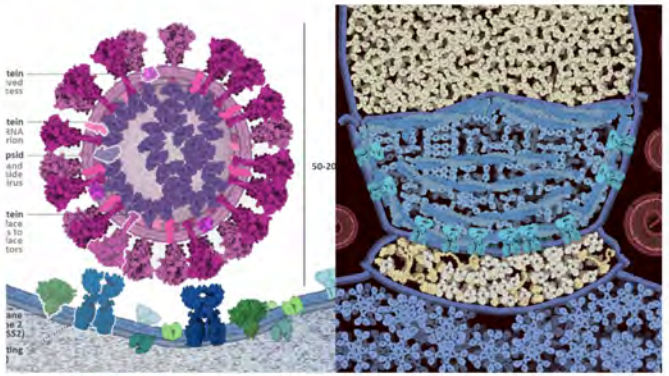


SARS-CoV-2 (2019-nCoV) coronavirus main pr

Download high quality TIFF image

COVID-19/SARS-CoV-2 Resources

03/25



Coronavirus CellPAINT Contest Winners in Art and Science at PDB-101

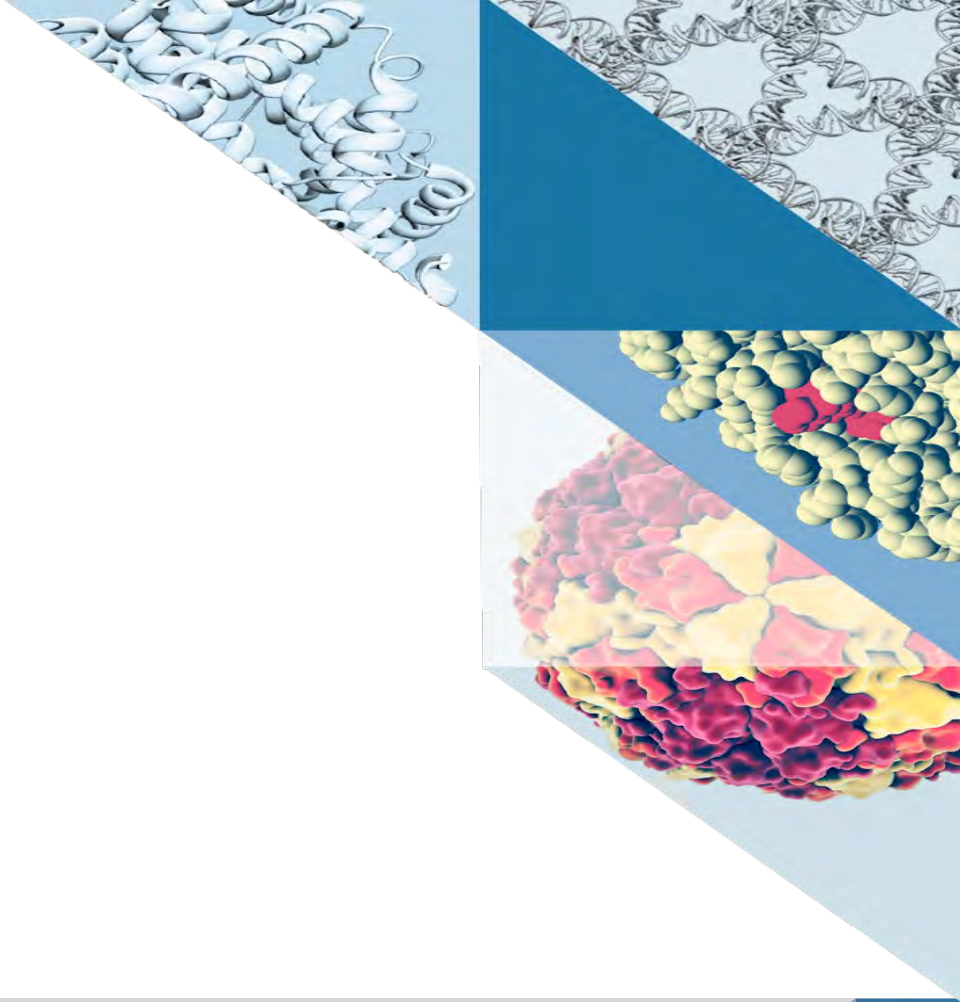
PDB Structures (as of July 1, 2020)

Access all SARS-CoV-2 PDB structures

Table of PDB structures complexed with Ligands of Interest (LOI); LOI Molecular Weight; LOI InCHIKey (TSV)

- New this week
- Main protease PDB structures
- Spike protein and spike receptors
- Papain-like SARS-CoV-2 structures
- Other SARS-CoV-2 structures
- PanDDA analysis structures and main protease with unliganded active site
- Contains SARS-CoV-2-reactive human antibody

RCSB PDB
PROTEIN DATA BANK



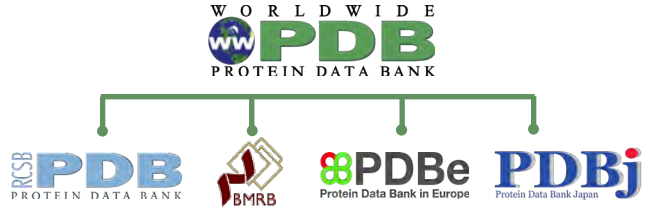
TRUST

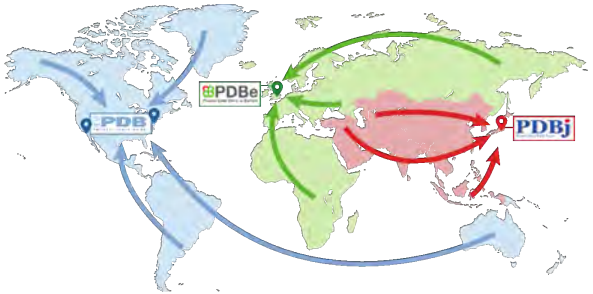
Sustainability

Who is looking after things?
Will that last?

Organizational Infrastructure

- Regional wwPDB partner data centers
- Global load-balancing and failover of deposition services
- Complimentary data access services

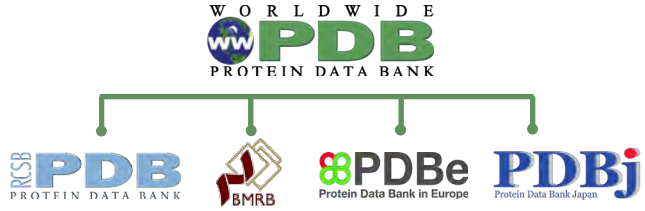


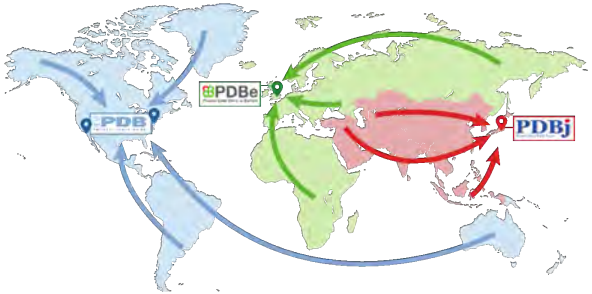


Regional partners responsible for data from:
RCSB PDB (US): Americas and Oceania
PDBe (UK): Europe and Africa
PDBj (Japan): Asia and Middle East

Continuity of Access

- 40+ year track record of funding support in US
- wwPDB organization provides for continuity of data and service access if a regional partner site should become unavailable
- Versioned repository delivery
- Snapshotting of primary data





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RCSB PDB
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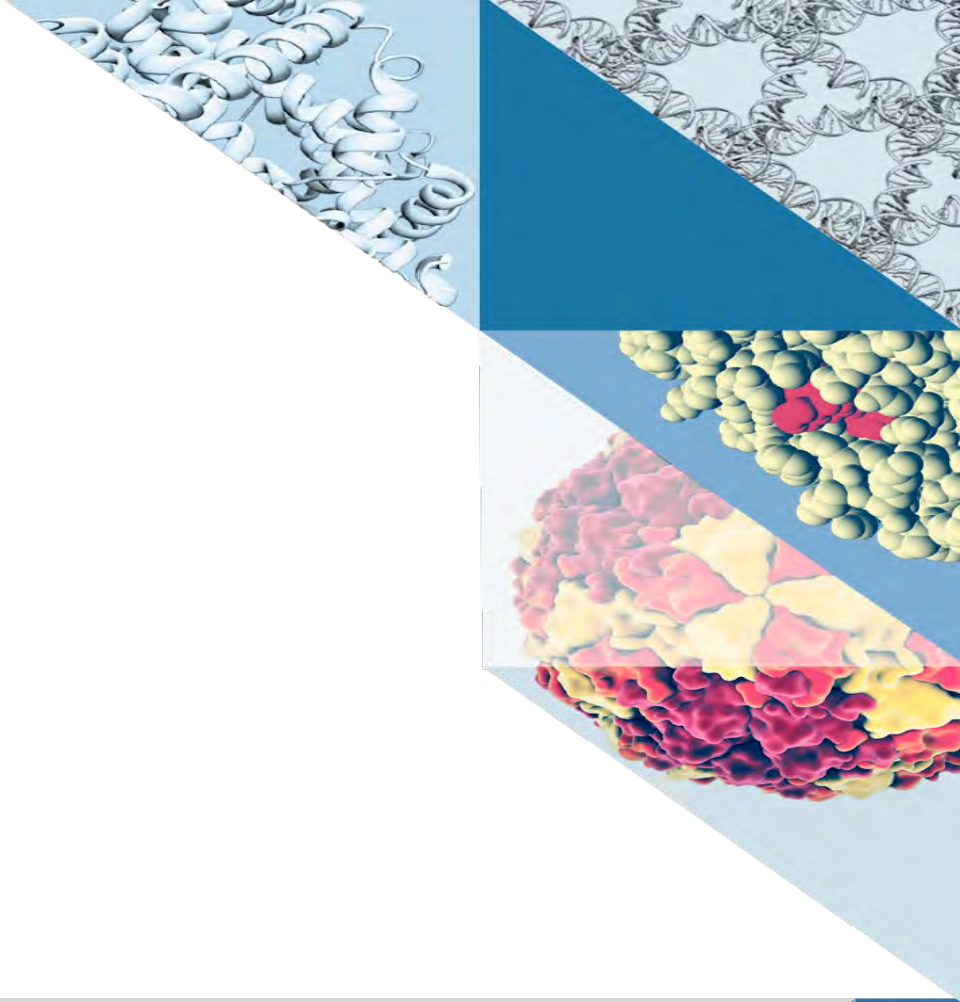


TRUST

Technology

Are you using cool tools?
Are they cool enough?
Are you in the cloud?
Can you get hacked?

Technical Infrastructure

- Data reference standards and ontologies in use
  - Lengthy and requiring consolidation from many sources
- Automated software development and deployment process
- Managing community software tools
- Workflow driven data processing and infrastructure management
- Capacity monitoring and management tools

INTERNATIONAL UNION OF BIOCHEMISTRY AND MOLECULAR BIOLOGY

IUPAC

openstack™ CLOUD SOFTWARE

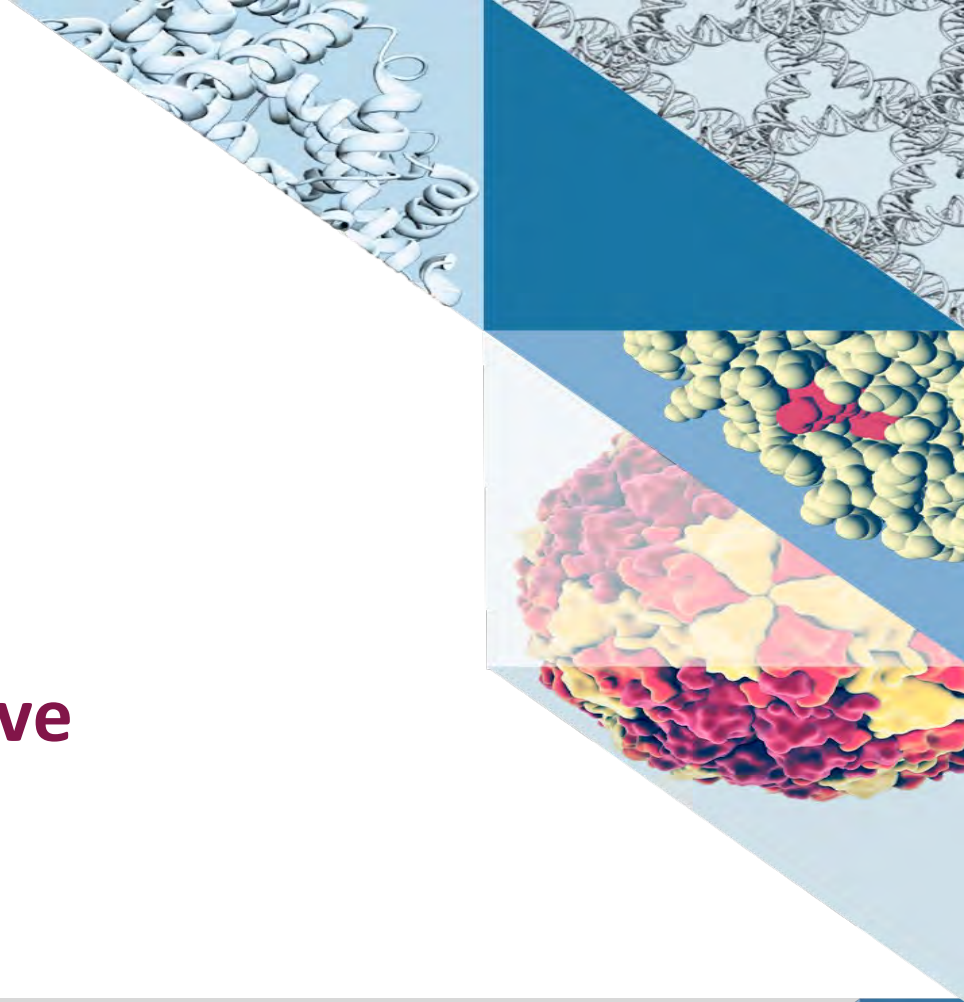
GitHub

CI/CD

Security

- Service availability, redundancy, disaster recovery
- Institutional security protocols and resources
- Application security protocols
  - Coding standards
  - Code review
  - Testing and deployment protocols
  - Version control

RCSB PDB
PROTEIN DATA BANK



Challenges from a Domain Perspective

FAIR and FACT are in our GENES

Findability (phenylalanine) + **A**ccessibility (alanine) +
Interoperability (isolucene) + **R**eusability (arginine)

FQRSTPAITLESPDIKYPLRLIDREIISHDTRRFRFALPSPQHILGLPVGQHIYLSARIDGNLVVRPYTPISSDDDKGFVDLV
IKVYFKDTHPKFPAGGKMSQYLESMQIGDTIEFRPSGLLVYQGKGKFAIRPDKKSNPIIRTVKSVGMIAGGTGITPMLQVI
RAIMKDPDDHTVCHLLFANQTEKDILLRPELEELRNKHSARFKLWYTLDRAPEAWDYGQGFVNEEMIRDHLPPPEEEPLVLMC
GPPPMIQYACLPNLDHVGHPTERCFVF

Human Erythrocyte NADH-cytochrome b5 Reductase (PDB 1UMK UniProt P00387)

Fair (phenylalanine) + **A**ccurate (alanine) +
Confidential (cysteine) + **T**ransparent (threonine)

GPGPEYQAQGLAMYLQENGIDCPKCKFSYALARGGCMHFACTQCRHQFCSGCYNAFYAKNKCPEPNCRVKKSLHGHHPRDC
LFYLRDWTALRLQKLLQDNNVMFNTEPPAGARAVPGGGCRVIEQKEVPNGLRDEACGKETPAGYAGLCQAHYKEYLVSLINAH
SLDPATLYEVEELETATERYLHVRPQPLAGEDPPAYQARLLQKLTEEVPLGQSIPRRRK

Human E3 ubiquitin-protein ligase RNF31 (PDB 4LJP UniProt Q96EP0)

… But Only TRST is Common

Transparency (threonine) +
Responsibility (arginine) +
User Focus (selenocysteine) +
Sustainability (serine) +
Technology (threonine)

SMLKRLSTEEATRWADSFDVLLSHKYGVAAFRAFLKTEFSEENLEFWLACEEFKKTRSTAKLVSKAHRIFEEFVDVQAPRE
VNIDFQTREATRKNLQEPSLTCFDQAQGKVHSLMEKDSYPRFLRSKMYLDLLS

Human Regulator of G-protein signaling RGS8 (PDB 5DO9 UniProt P57771)

We all need to work harder to master
- User Focus -

RCSB PDB Team

RCSB PROTEIN DATA BANK

RCSB.ORG

info@rcsb.org

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National Institute of Allergy and Infectious Disease,
and National Cancer Institute, (R01GM133198),
and the US Department of Energy (DE-SC0019749)

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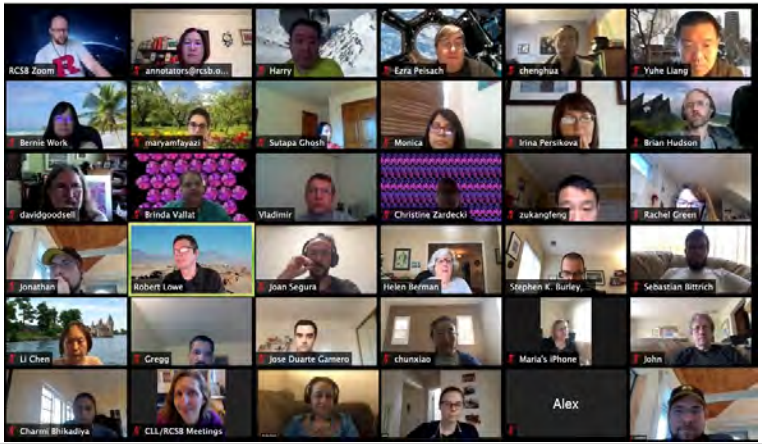
WORLDWIDE PDB PROTEIN DATA BANK

RCSB PDB is a member of the Worldwide Protein Data Bank partnership (wwPDB; **wwpdb.org**)



Questions & Answers

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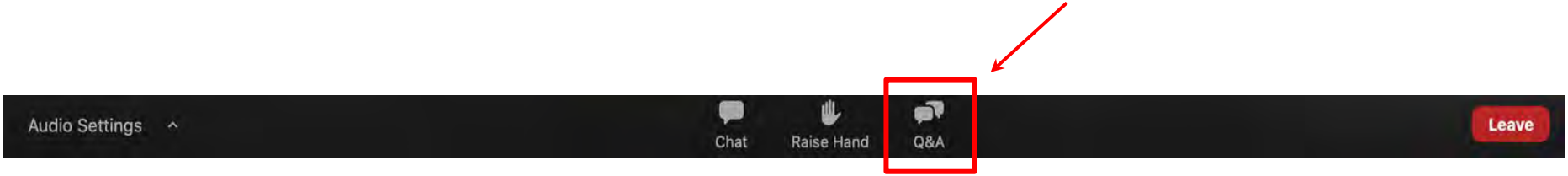

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RDC DRC Research Data Canada – Données de Recherche Canada

Funder Story: A Use Case

Presented by Mark Leggott

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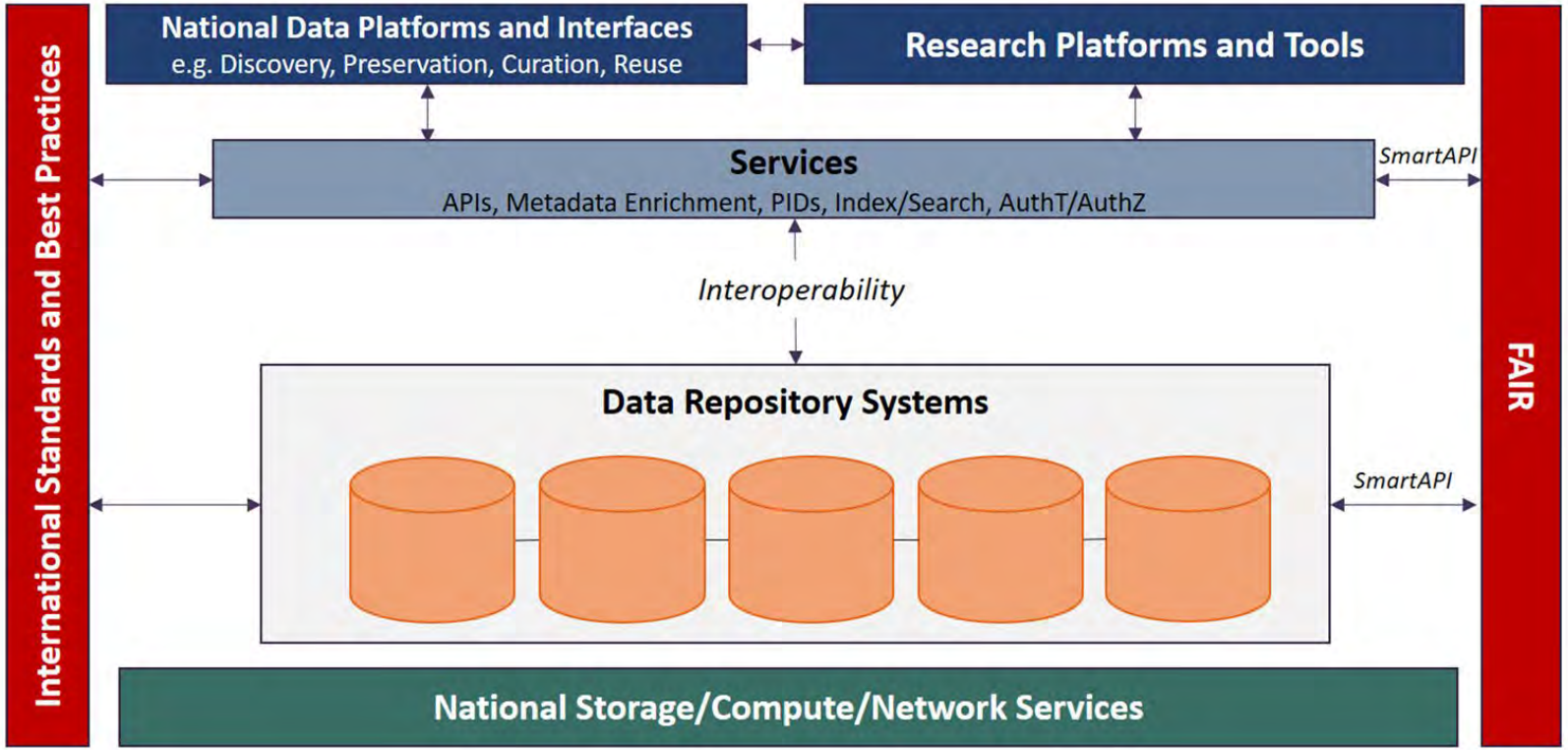
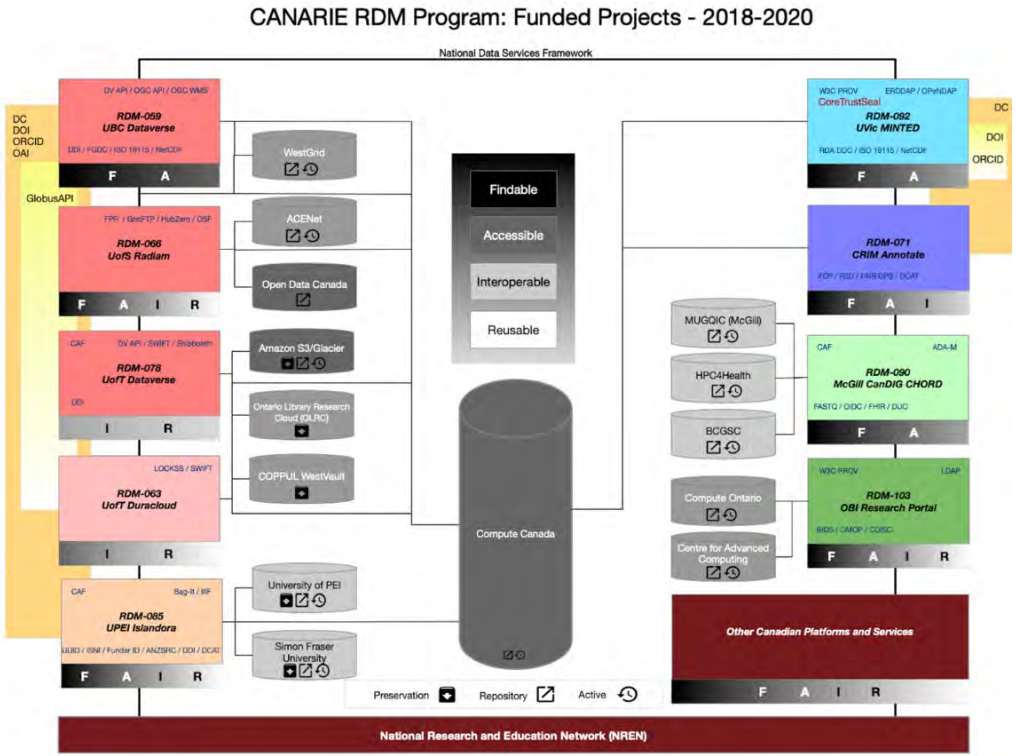
CANARIE RDM Funding (2018 Program)

- CANARIE Research Data Management Funding Program Launched 2018
- Funding call based on Community Consultation
- Identified 8 key “gaps and opportunities” in the ecosystem
- Also highlighted adherence to
  - the FAIR Principles
  - the National Data Services Framework (NDSF)
- Applicants were required to address one or more of the gaps, as well as FAIR and NDSF
- 9 Projects selected, completed in March 2020

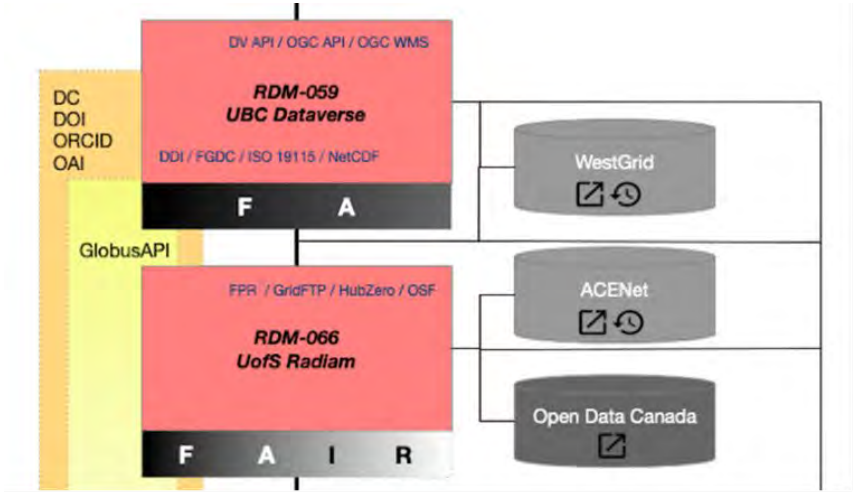
RDM Call 1 Guidance

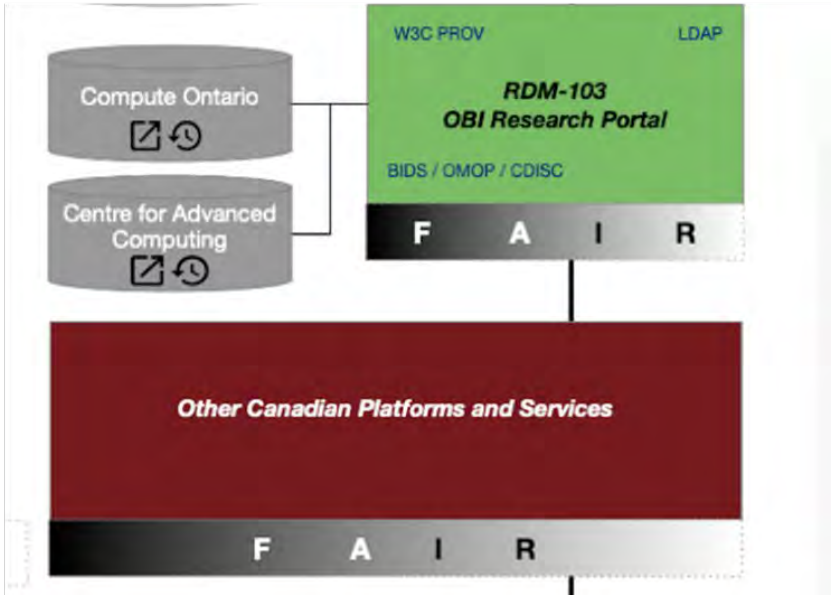


RDM Call 1 Projects



RDM Call 1 Project Intersections





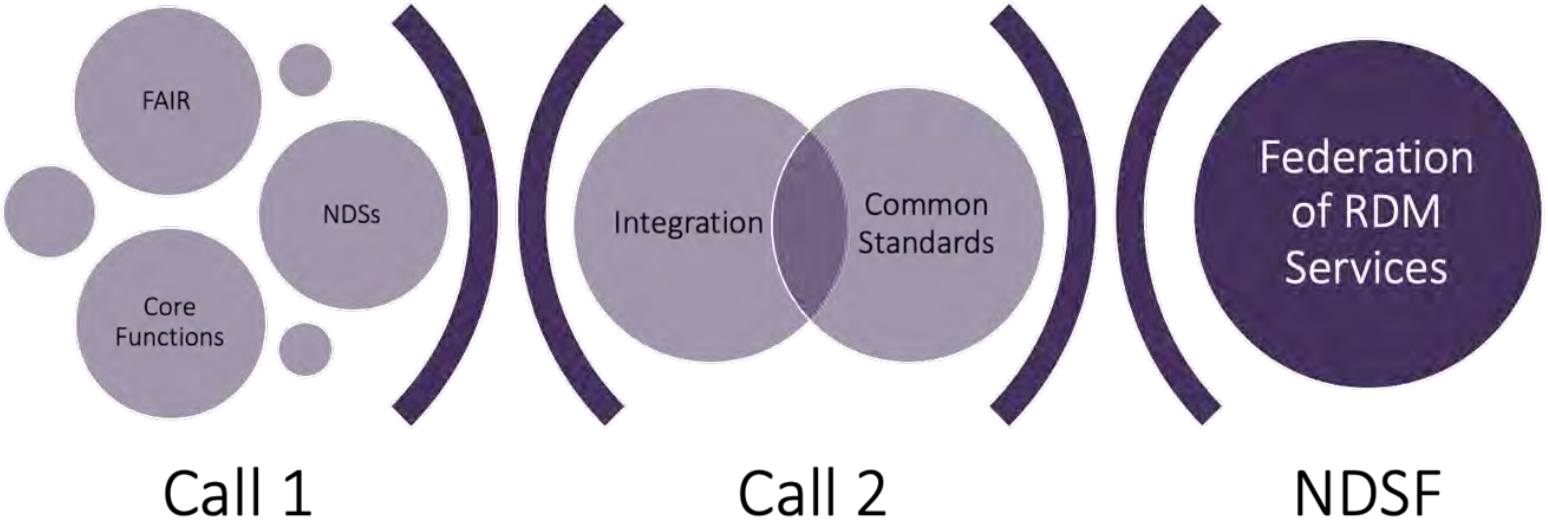
CANARIE RDM Call 2 (2019)

- Call 2 launched late 2019
- Built on parameters from Call 1, reinforcing FAIR+NDSF focus
- Added requirement to create/enhance interoperability between multiple disparate systems
- Encouraged integration between research platforms and repositories
- 4 projects selected, development Apr 2020-Mar 2022

Research Data Canada’s NDSF

- National Data Services Framework
  - a conversation with all stakeholders at all levels;
  - agreement on best-practices, standards and protocols;
  - a suite of interoperable services and resources.
- Summits held 2017, 2019, 2020
- Facilitates the development of national research infrastructures
- Intersects with CANARIE RDM funding, as well as efforts of the emerging **N**ew **D**igital **R**esearch **I**nfrastructure **O**rganization (NDRIO), other Canadian funders and data management/research software organizations

Building Synergies with National Efforts



Evolution Towards TRUSTed Services

- Goal is to continue to evolve the national conversation, and work with funders to integrate support for TRUST and national data repositories into ongoing efforts
- Portage Data Repositories Expert Group is working on a multi-stakeholder proposal (e.g. Portage, NDRIO, RDC, WDS-ITO) to define a new call for support and funding

Questions & Answers

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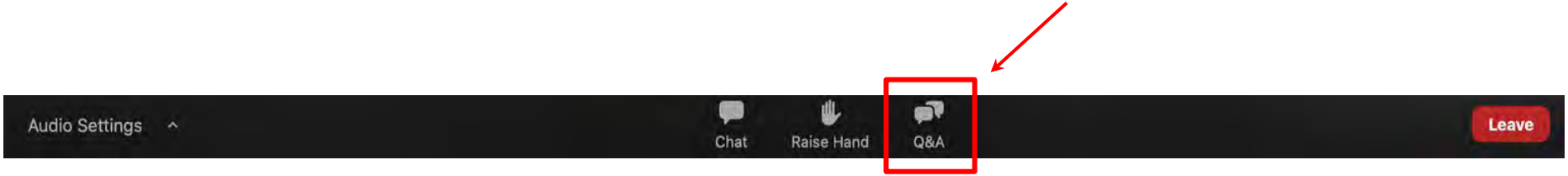

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RDC DRC Research Data Canada – Données de Recherche Canada

Stakeholder Panel

Moderated by Mustapha Mokrane

Panelists:

- TRUST author – Robert Downs
- Funder – Mark Leggott
- Research Community – Shelley Stall
- Repository Manager – John Westbrook
- Publisher – Varsha Khodiyar

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Stakeholder Panel

Question 1:

What would you see as the main challenges for implementation within your stakeholder community?

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Stakeholder Panel

Question 2:

What would you consider a sign of success and what would be the impact of the TRUST Principles in the short and longer term?

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Stakeholder Panel

Question 3:

How can we as a community help the TRUST Principles succeed?

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Wrap-up and Ways Forward

Any remaining questions?

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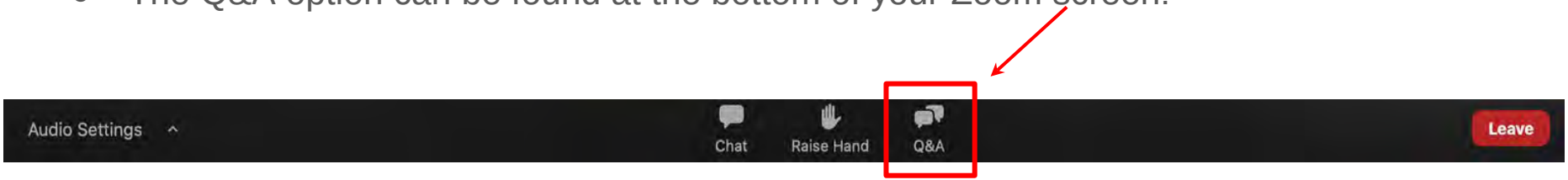

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Thank you!

For further information:

- Read ‘The TRUST Principles for digital repositories’ in *Nature Research’s Scientific Data*: https://www.nature.com/articles/s41597-020-0486-7
- DOI: https://doi.org/10.1038/s41597-020-0486-7
- For further details and endorsements, see the RDA website: https://www.rd-alliance.org/rda-community-effort-trust-principles-digital-repositories-0
- Find this slide deck at https://bit.ly/TRUSTSymposium

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