



2019 APEC Business Ethics for SMEs Forum

SANTIAGO DE CHILE | 9-10 SEPTEMBER





PLENARY SESSION



OPENING SESSION

Mr. Patrick Kirwan

*U.S. Delegate, APEC SME Working Group
Director, Trade Promotion Coordinating
Committee Secretariat
U.S. Department of Commerce*



PLENARY SESSION



CONSENSUS FRAMEWORKS: PLATFORMS FOR A CULTURE OF ETHICS AND INTEGRITY

*Ms. Diane Biagianti
Chief Responsibility Officer
Edwards Lifesciences*



Marco de Consenso Chileno Chilean Consensus Framework

*Para la Colaboración Ética Multisectorial en Los
Sectores Farmacéuticos y de Dispositivos Médicos*

*For Multi-Stakeholder Ethical Collaboration in the
Pharmaceutical and Medical Device Sectors*



Chile Consensus Framework:

Multistakeholder Process for Ethical business practices

Gastón Fernández Schiaffino
Head of Regulatory Affairs Division
Undersecretariat of International Economic Affairs
Ministry of Foreign Affairs



The Asia-Pacific Economic Cooperation (APEC) Forum

- **Support sustainable economic growth and prosperity in the Asia-Pacific region.**
 - **Engine of global economic growth in the 21st century**
 - **Trade liberalization and Regional integration**
 - **Support for the Multilateral Trade System and the WTO**
 - **Promote policies in favor of open trade and investments**
 - **Proactive relationship with the business community: ABAC**
-
- **39% of the global population (2.9 billion people)**
 - **50% of global trade annually USD 16 Trillion**
 - **60% of Global GDP USD \$45 Trillion**
 - **Top 3 GDP (USA, Japan and China)**
 - **Top 5 population (China, Indonesia and USA)**

1. Trade Policy
2. The Chile Consensus Framework Process
3. Roadmap-Challenges

Some numbers...

28

FTA

64

Economies

86%

Global GDP

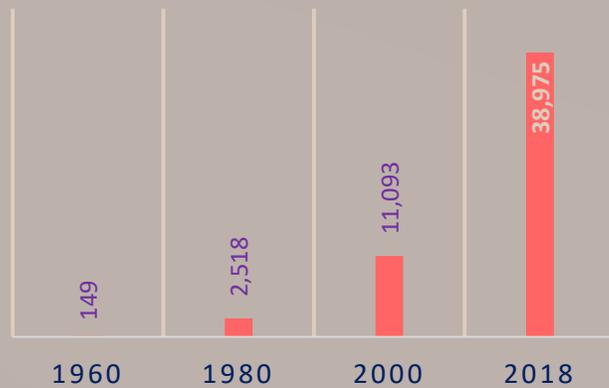
63%

Global Population

57%

Goods and Services/ GGP

Record Non Copper Export us\$ Million



1^{er}

EXPORTER 2018



Fresh Cherries | Grapes Blueberries | Salmon |

8.080

Companies
3.378 SMEs

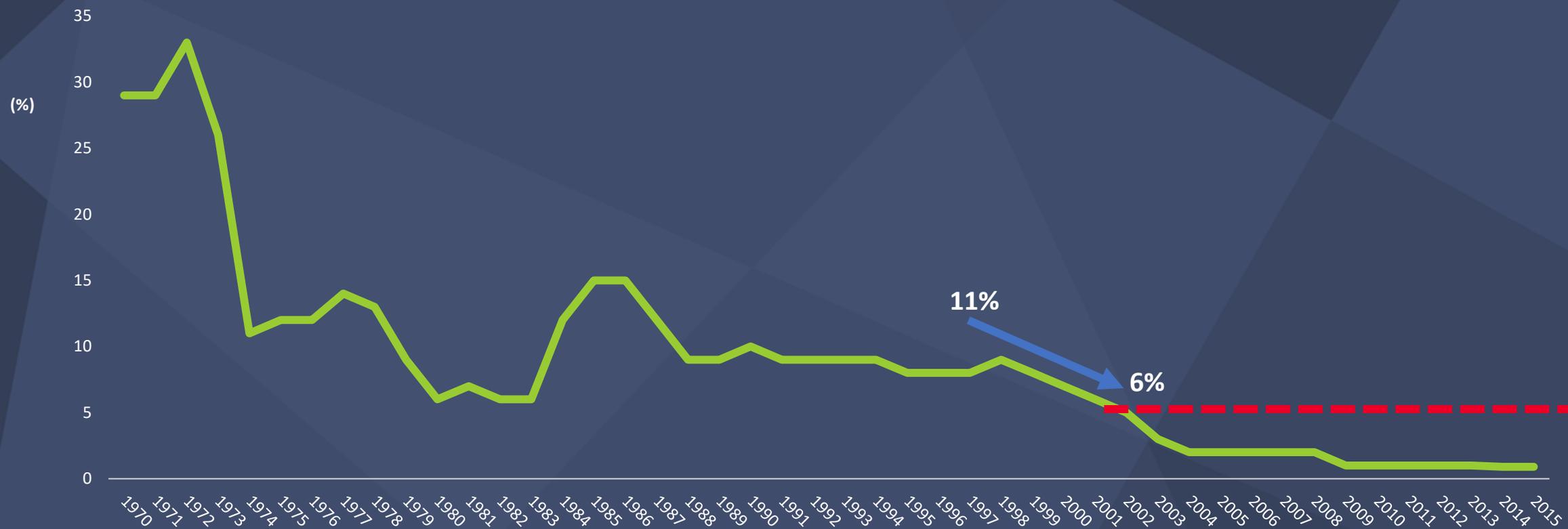
1,2

Jobs

95%

CHINA (35%)
US (14%)
JAPAN (10%)





FIGURES BY 2018

66%

OF TOTAL TRADE WITH THE WORLD

59%

OF CHILE'S IMPORTS COME FROM APEC MEMBER ECONOMIES

59%

OF FOREIGN INVESTMENT IN CHILE COMES FROM THE APEC REGION

27%

OF CHILE'S INVESTMENT OUTFLOWS ARE IN APEC MEMBER ECONOMIES

73%

OF CHILE'S EXPORTS GO TO APEC MEMBER ECONOMIES

10%

ANNUAL GROWTH OF CHILE EXPORTS TO APEC MEMBER ECONOMIES SINCE 1994

Since Chile joined APEC in 1994, exports to the region have increased by **790%**

SMEs EXPORTS TO APEC

57%

US \$ 895

2300

PORCENTAJE

IN VALUE

IN NUMBER

1. Trade Policy
2. The Chile Consensus Framework Process
3. Roadmap-Challenges

1. **DIGITAL SOCIETY**
 2. **INTEGRATION 4.0**
 3. **SUSTAINABLE GROWTH**
 4. **WOMEN, SMEs, AND INCLUSIVE GROWTH**
- Visualizing / enhancing the role SMEs
 - Promote the development, growth and competitiveness of SMEs.

CHILE CONCESUS FRAMEWORK PROCESS

- **Engagement**
- **Heterogeneous: Recognition of different realities**
- **Cooperation**
- **Teamwork begins by building trust**
- **Commitment**
- **Alling toward a common vision**
- **Binding v/s Non-binding**
- **Public-Multi stakeholder Approach**
- **Understanding the trade costs of regulatory divergence (challenges and opportunities)**

1. Trade Policy
2. The Chile Consensus Framework Process
3. Roadmap-Challenges

Roadmap-Challenges

- National / International Coordination
- Leadership
- Momentum
- Multi stakeholder approach
- Commitment

it takesto tango



Gastón Fernández Schiaffino
Head of Regulatory Affairs Division
Undersecretariat of International Economic Affairs
Ministry of Foreign Affairs of Chile.





PLENARY SESSION



2019 APEC BUSINESS ETHICS FOR SMES LIGHTHOUSE AWARD

*Adrian Cosenza, Chair
Australian Ethical Healthcare Alliance*



OFFICIAL PLENARY PHOTOGRAPH 9:45 – 10:00



PLENARY SESSION

IMPLEMENTING CONSENSUS FRAMEWORKS: UPDATES FROM THE REGION 10:00 – 10:30



The Australian Consensus Framework for Ethical Collaboration in the Healthcare Sector

Australian Ethical Health Alliance

Adrian Cosenza

AEHA Chair

Australian Orthopaedic Association CEO

Alison Verhoeven

AEHA Steering Committee

Australian Healthcare and Hospitals
Association CEO



AUSTRALIAN
ETHICAL HEALTH
ALLIANCE

AEHA



What is the Australian Consensus Framework for Ethical Collaboration in the Healthcare Sector (ACF)?

- A consensus of shared values and ethical principles that form the basis of collaboration and interaction among organisations in the Australian healthcare sector
- A voluntary, sector-lead initiative
- Inclusive and embracing – all parties welcome to participate, listen and join ACF activities





What does it aim to achieve?

- Promote collaboration and interaction
- Encourage better dialogue, trust and respect
- Promote public confidence and trust





When was it launched?

- Australian delegation officially presented the *Australian Consensus Framework for Ethical Collaboration in the Healthcare Sector* at the APEC Business Ethics for SME Forum, in Tokyo on **20 July 2018**





Who is involved?

- 71 member organisations:
 - Biopharmaceutical industry
 - Educators
 - Government authorities
 - Healthcare professionals
 - Hospitals/healthcare centres
 - Medical device industry
 - Patient communities
 - Third parties/distributors.



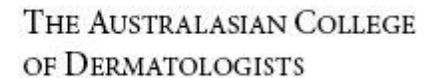
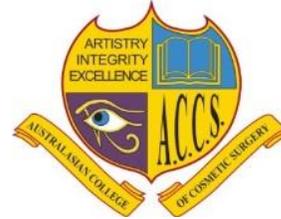


- Support and endorsement from **every state and territory** and the Federal Minister of Health





The signatories





The signatories





The signatories



AUSTRALASIAN COLLEGE OF
SPORT AND EXERCISE PHYSICIANS



UROLOGICAL SOCIETY
OF AUSTRALIA
AND NEW ZEALAND



The Australian Hand
Surgery Society



RACP
Specialists. Together
EDUCATE ADVOCATE INNOVATE



Australian & New Zealand
College of Paramedicine



BUPA



THE ROYAL AUSTRALASIAN
COLLEGE OF DENTAL SURGEONS



AUSTRALIAN
SARCOMA
GROUP
A Multidisciplinary Cancer Group



Australian College for
Emergency Medicine



Private Healthcare Australia
Better Cover. Better Access. Better Care.

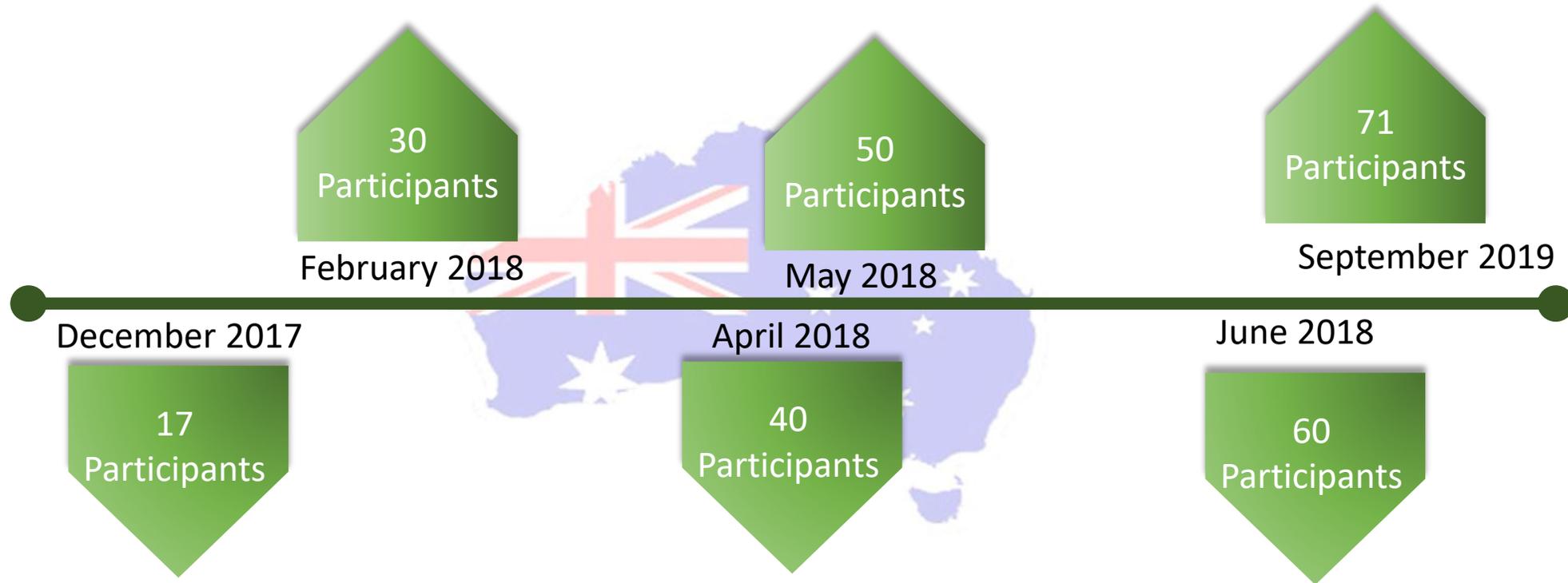


Melanoma and Skin
Cancer Trials Limited





Rapid Growth in Participation





Who does the Framework represent?

71 signatories represent approximately:

200,000

health professionals,
employees and
trainees

3.2 million

consumers/patients



The Framework

- Signatories agreed to a simple yet effective set of ethical principles:
 - **Substantive Principles**
 - **Procedural Principles**

Australian Consensus Framework
for Ethical Collaboration in the
Healthcare Sector



A Consensus Statement of Shared
Values and Ethical Principles
for Collaboration and Interaction
Among Organisations
in the Healthcare Sector



Primary role of the Framework

Designed to:

- Assist development and modification of policies and processes.
- Implement the principles articulated in the ACF
- Complement and strengthen the importance of collaboration



Not designed to:

- Focus on individuals
- Develop prescriptive policies
- Develop resources for specific organisations
- Mandate/monitor/regulate anything other than the reporting of activities related to the ACF



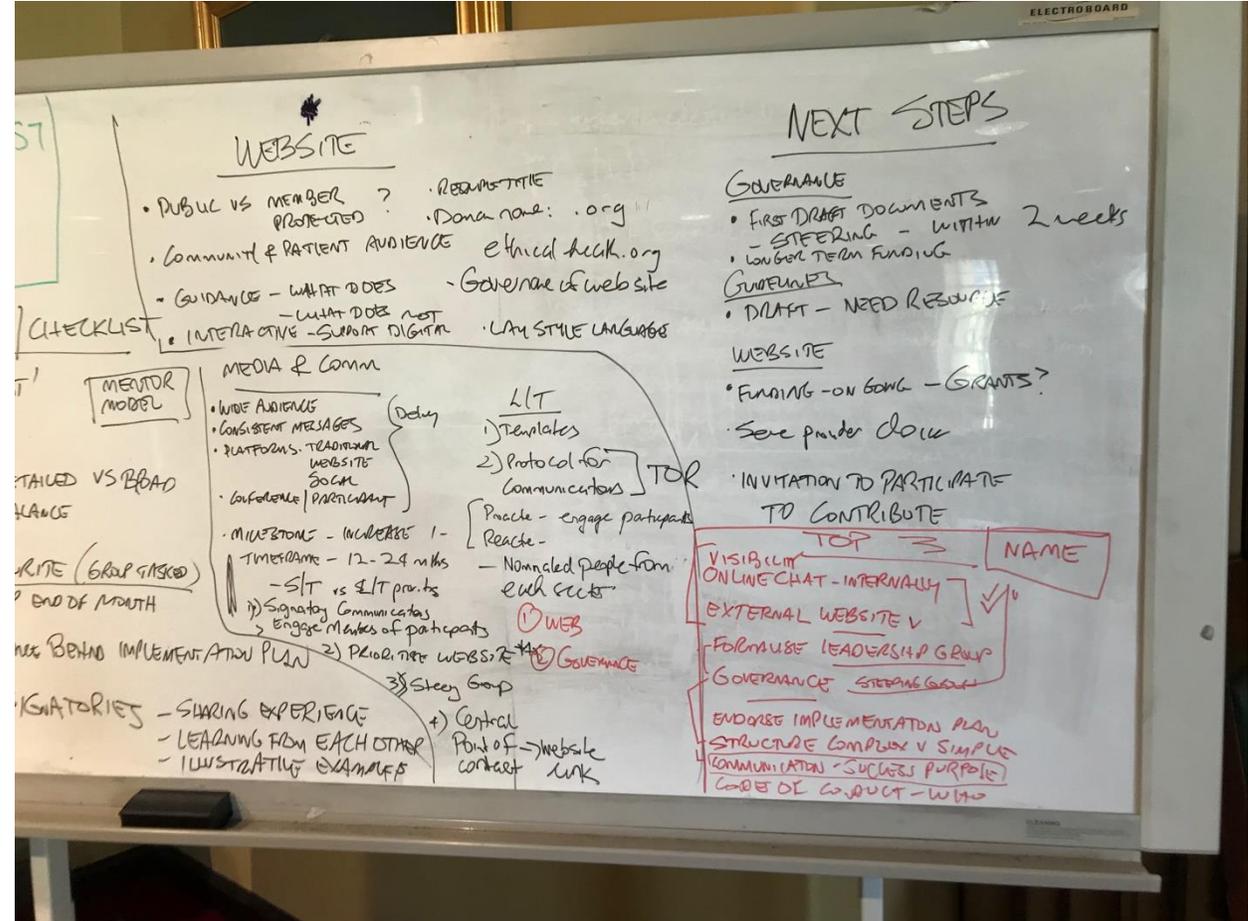
Primary role of the Framework

- Important for signatories to be prepared to be self reflective and self accountable
- Not aimed at being judgmental of individual organisations, but rather an exercise to ask members to measure themselves against the ACF
- Aim is to find common good and common purpose rather than establishing a process by which to reprimand, discipline etc



ACF workshops

- Since the initiative's launch, organisations have met on three occasions:
 - January (Sydney)
 - April (Melbourne)
 - July (Canberra)
- Participants ranging between 25 to 40 organisations





What is the Australian Ethical Health Alliance (AEHA)?

- The body to guide the implementation of the ACF
- Consists of those member organisations who are signatories to the ACF

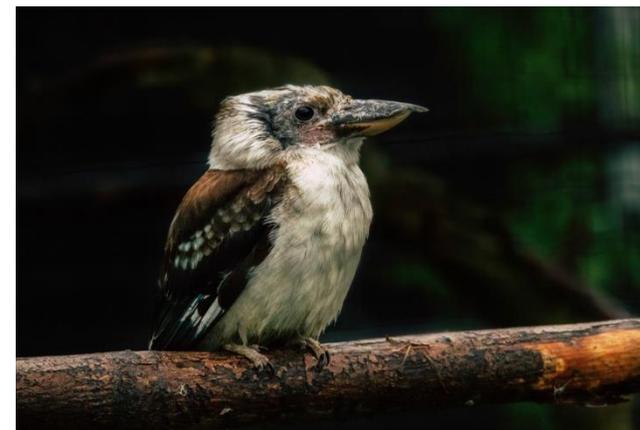




AEHA Steering Committee

Members of the Committee include:

- Adrian Cosenza, Australian Orthopaedic Association (Chair)
- Alison Verhoeven, Australian Healthcare and Hospitals Association
- Deborah Monk, Medicines Australia
- Jane Fitzpatrick, Australasian College of Sport and Exercise Physicians
- Leanne Wells, Consumers Health Forum of Australia
- Tracey Duffy, Department of Health
- Ian Burgess, Medical Technology Association of Australia
- Ian Kerridge, Royal Australasian College of Physicians
- Wendy Lipworth, Praxis Australia
- Peter Subramaniam Australian and New Zealand Society for Vascular Surgery
- Mary Warner, Department of Health
- Carolyn Stapleton, Australian College of Nursing
- Chris Ho, Skin Cancer College of Australasia
- Rachel Yates, Universities Australia.





ACF aims are supported by the **AEHA Implementation Plan**

- The Plan outlines the steps to enact the work of AEHA including:
 - Development of a structure for AEHA governance
 - Development of guidelines and self-evaluation form for member organisations to assist them in aligning their policies and processes with the ACF
 - Development of communication and engagement strategies.





Governance

Aim:

- To determine a governance structure for the Australian Ethical Health Alliance
- To develop Terms of Reference for the Australian Ethical Health Alliance Steering Committee
- To formalise the appointments of the Steering Committee.

<u>Milestone</u>	<u>Deliverables and Measures</u>
1. Develop governance document for the Australian Ethical Health Alliance	30 June 2019 – Complete
2. Develop a Terms of Reference for Australian Ethical Health Alliance steering committee	30 June 2019 – Complete
3. Determine whether the Australian Ethical Health Alliance should be established as a legal entity	30 June 2019 – Complete



Implementation Guide and Self-Evaluation Form

Aim:

- To develop a guide that assists organisations with aligning their structure, policies and processes with the ACF principles by developing an implementation guide
- To develop a template that can be used by member organisations to self-evaluate on their activities related the ACF that is fair, practical, generative and non-punitive, and applicable to all signatories are applicable to all signatories.

<u>Milestone</u>	<u>Deliverables and Measures</u>
1. Form a drafting group that will write the Implementation Guide and Self-Evaluation Form	31 May 2019 – Complete
2. Develop and circulate a draft outline of the Implementation Guide and Self-Evaluation Form	30 June 2019 – Complete
3. Identify and confirm member organisations that will be involved in a pilot of the Implementation Guide and Self-Evaluation Form	30 August 2019 – Complete
4. Assess the outcome of the pilot and determine if the Implementation Guide and Self-Evaluation Form can be applied to all signatories	28 February 2020
5. Finalise the Implementation Guide and Self-Evaluation Form and promote on the group's website	30 September 2019 – Complete



Communication and Engagement

Aim:

- To grow the Australian Ethical Health Alliance
- To raise awareness of the Australian Ethical Health Alliance and the ACF
- More specifically, to develop a website and a media and communications plan, and develop a process for holding annual workshops and other events.

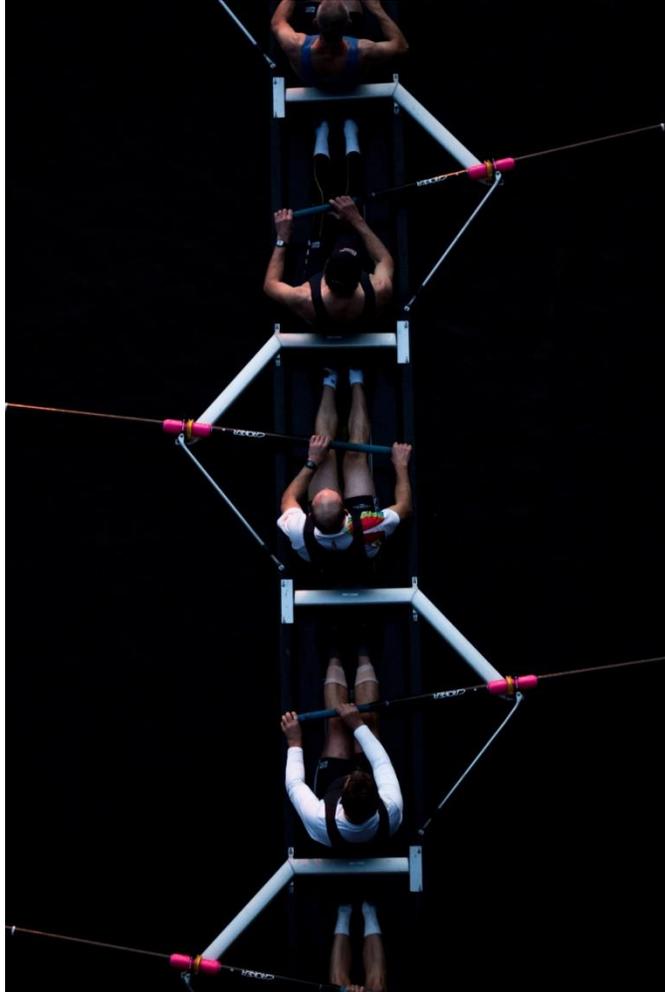
<u>Milestone</u>	<u>Deliverables and Measures</u>
1. Develop a media/communications working group	30 June 2019 – Complete
2. Determine the governance process for overseeing website design and content	30 June 2019 – Complete
3. Prepare material on Australian Ethical Health Alliance and ACF that can be disseminated by member organisations for publicity purposes	Sep 2019 – Ongoing from Sept 2019
4. Prepare material on Australian Ethical Health Alliance and ACF that can be used by member groups at conferences	Sep 2019 – Ongoing from Sept 2019
5. Identify relevant conferences/events at which member organisations can present and/or organise satellite workshops/symposia	Sep 2019 – Ongoing from Sept 2019
6. Conduct a needs analysis assessment on an annual workshop/seminar	Sep 2019 – Complete
7. Develop an AEHA media and communications plan, including a social media plan (to commence from April 2020) and a request for member organisation to advocate for the ACF principles	Sep 2019 – Complete



Communication and Engagement

- Publication of the journey and insights already well progressed

8. Develop a protocol for how media statements and communications should be developed and released	Sep 2019 – Steering Committee agenda 1 Nov 2019
9. Prepare an academic article for publication	Sep 2019 – Complete
10. Develop a website	Sep 2019 – Complete
11. Launch website	September 2019 – Complete
12. Nominate a person as the central point of contact for all media queries and allocate spokespersons	April 2020 – Steering Committee agenda 1 Nov 2019



Guide for Member Organisations

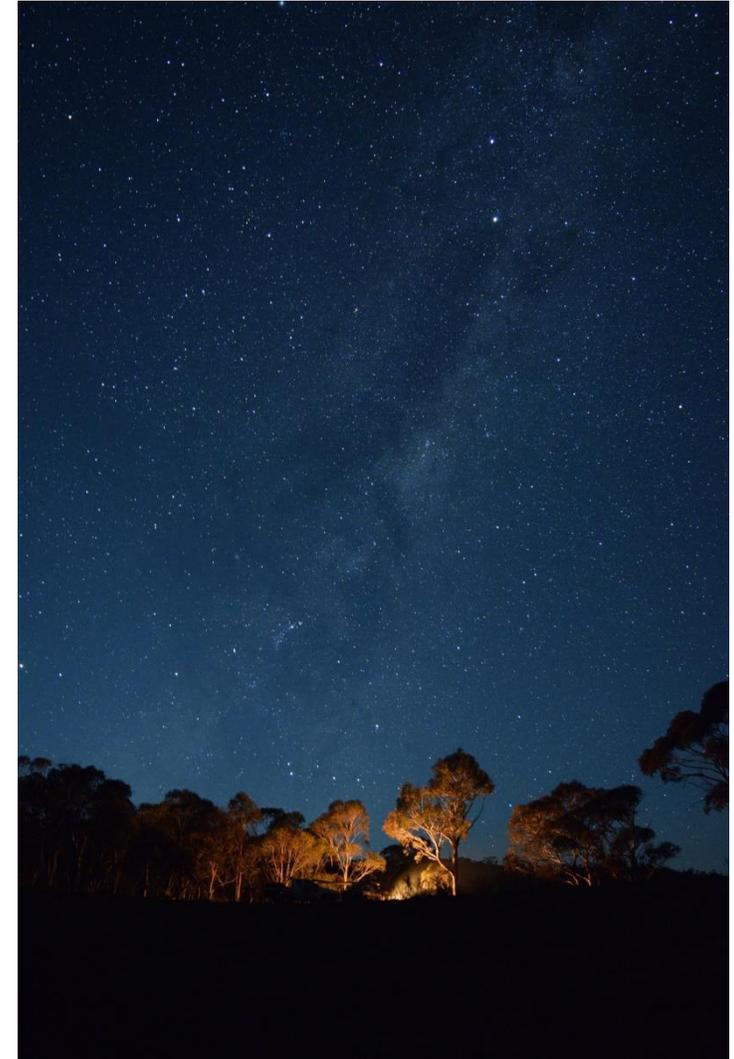
- Improving ethical practice and culture requires clear directions on how to implement principles
- *Guide for Member Organisations* provides practical advice and examples as to how organisations might align their practices and policies
- Activities not prescriptive
- All are asked to submit an *Annual Self-Evaluation Form* to be shared amongst member organisations
- Document pilot is planned



Where to from here?

The goal over the next 12 months:

- Encourage the implementation of the ACF principles
- Promote strategies on implementing ethics
- Significantly progress the AEHA Implementation Plan
- Engage member organisations
- Raise awareness of the Alliance
- Grow the member organisations of AEHA.





Lessons...Recommendations for APEC regions progressing a framework



- Allow organisations at any stage of their progress on ethics to join
- Ensure development and implementation is voluntary, consultative and collaborative
- Ensure principles are developed with an awareness of a potential broad-spectrum member group



Lessons...Recommendations for APEC regions progressing a framework



- Clear value proposition – relevance to existing ethics framework
- Senior political support early in process
- Use of language – commonly understood- non academic/non technical
- Flexibility in ‘ownership’ for each participant
- Use an ethical activities pilot to validate the relevance of implementation activities



Challenges...what we do not know...

- Will the Australian Ethical Health Alliance genuinely drive meaningful changes in ethical practices
- How will we measure success?
- Is positive collaboration sustainable?
- Will an informal structure of governance and communication serve the community well once move beyond the enthusiasm in creating the movement?



The Australian Consensus Framework for Ethical Collaboration in the Healthcare Sector

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IMPLEMENTING CONSENSUS FRAMEWORKS: UPDATES FROM THE REGION 10:00 – 10:30



IMPLICATIONS OF HEALTHCARE TECHNOLOGICAL DISRUPTION ON ETHICAL BUSINESS CONDUCT IN THE APEC REGION BY 2030



Dr. Julien Durand, JD, MBA

Executive Director Ethics & Compliance, Amgen

Chair of eBIC Future Health Technologies WG, IFPMA



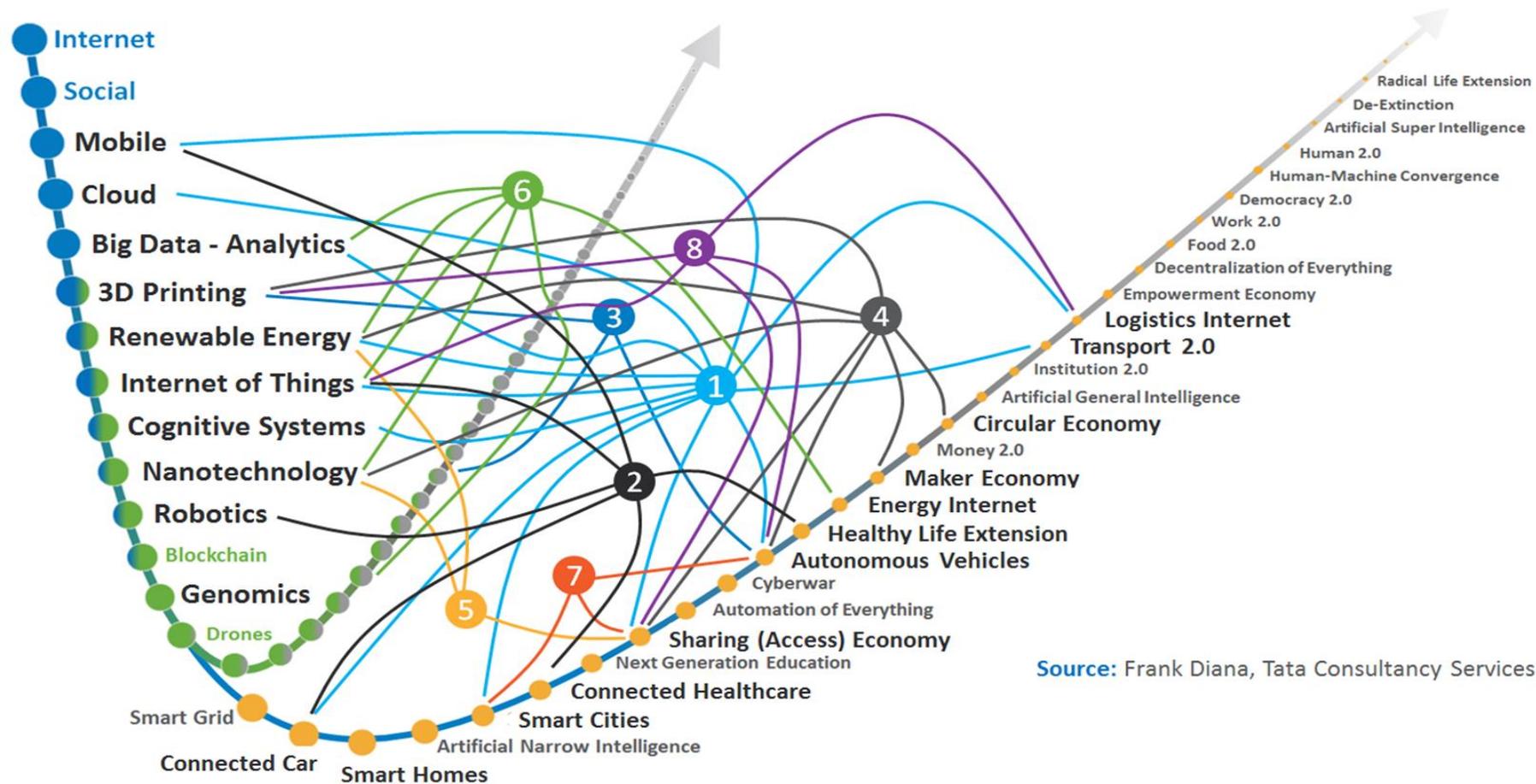
APEC will be the World's innovation powerhouse by 2030



- Top 10 largest Digital Tech companies
- 70% of Unicorns & promising SMEs
- 70% of global AI expertise
- 60% of global Biotech/Medtech expertise



Exponential Techs combining in unprecedented ways by 2030



Source: Frank Diana, Tata Consultancy Services



Biopharma & Medical Device most impacted by these Techs

1. DIGITAL HEALTH & EXTENDED REALITIES

- Internet of Things & wearables
- Mobile health apps
- Blockchain
- Telemedicine
- Augmented & virtual reality
- Digital biomarkers

3. HEALTH ROBOTICS & MEDICAL DEVICES

- Delivery & diagnostic devices
- Robotic surgery
- Brain-Computer Interfaces
- Exoskeleton & bionic prosthetics
- Nanotechnologies
- Drones for health

2. MACHINE INTELLIGENCE (AI)

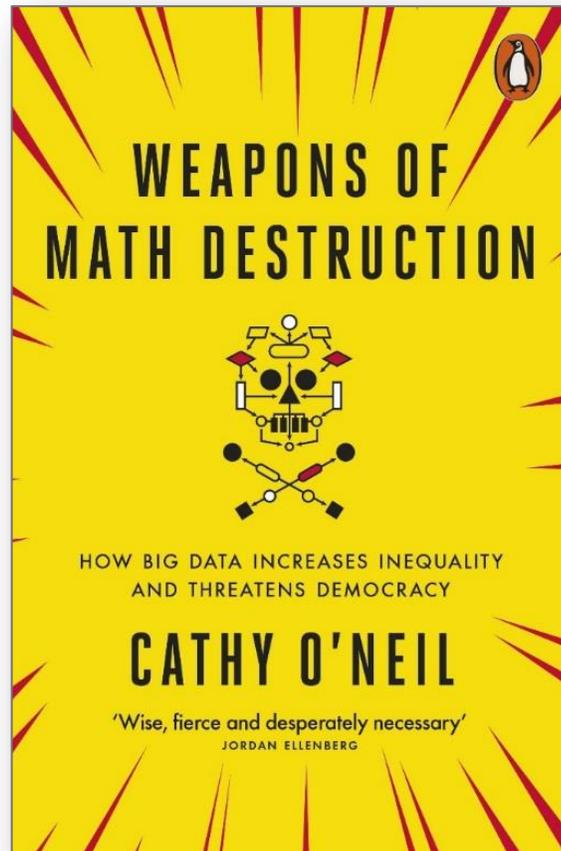
- Natural Language Processing
- Machine Learning
- Virtual nurses & robo-doctors
- Robotic Process Automation
- Big health data
- Virtual reps & employees

4. GENOMICS & ADDITIVE TECHNOLOGIES

- Gene sequencing
- Gene editing
- Gene therapies & stem cells
- Bioprinting
- Prosthetics
- Proteomics



Ethics of Algorithms



What if AI in health care is the next asbestos?

Jun 19, 2019

ETHICS AND GOVERNANCE OF AI



HARVARD
UNIVERSITY



Jonathan Zittrain

SHARE TO



Artificial intelligence is often hailed as a great catalyst of medical innovation, a way to find cures to diseases that have confounded doctors and make health care more efficient, personalized, and accessible. But what if it turns out to be poison?

“I think of machine learning kind of as asbestos,” said BKC’s Jonathan Zittrain. “It turns out that it’s all over the place, even though at no point did you explicitly install it, and it has possibly some latent bad effects that you might regret later, after it’s already too hard to get it all out.”



Algorithms are changing the practice of medicine

For the First Time, a Robot Passed a Medical Licensing Exam

In the future, HCPs will become reluctant to perform diagnostics or surgery without machine assistance

We should treat algorithms like prescription drugs

Man told he's going to die by doctor on video-link robot

By Andy Coravos, Irene Chen, Ankit Gordhandas & Ariel Dora Stern · February 14, 2019

🕒 9 March 2019

[f](#) [💬](#) [🐦](#) [✉](#) [Share](#)

TECHNOLOGY

How Do You Regulate a Self-Improving Algorithm?

For health care, the answer is a matter of life and death.

JONATHAN KAY · OCT 25, 2017

Australian Researchers Have Just Released The World's First AI-Developed Vaccine

25,089 views | Feb 11, 2019, 12:52pm

Can You Sue An Algorithm For Malpractice?

Time to Take 'Hippocratic Oath' for Engineering

AI system 'should be recognised as inventor'

Medical Devices Hit By Ransomware For The First Time In US Hospitals



Bioethics

Scientists call for global moratorium on gene editing of embryos

DNA testing firms are cashing in our genes. Should we get a cut?

Japan approves first human-animal embryo experiments

Genetic engineering and biological weapons

Don't change your DNA at home, says America's first CRISPR law

Technoethics



New technologies for the brain require ethical approaches to innovation

June 26, 2019 8.36pm BST

South African doctors perform world's first 3D middle ear transplant

WorldViews

An euthanasia expert just unveiled his 'suicide machine' at an Amsterdam funeral fair

Inside the Crypto World's Biggest Scandal

Saudi Arabia's robot citizen is eroding human rights

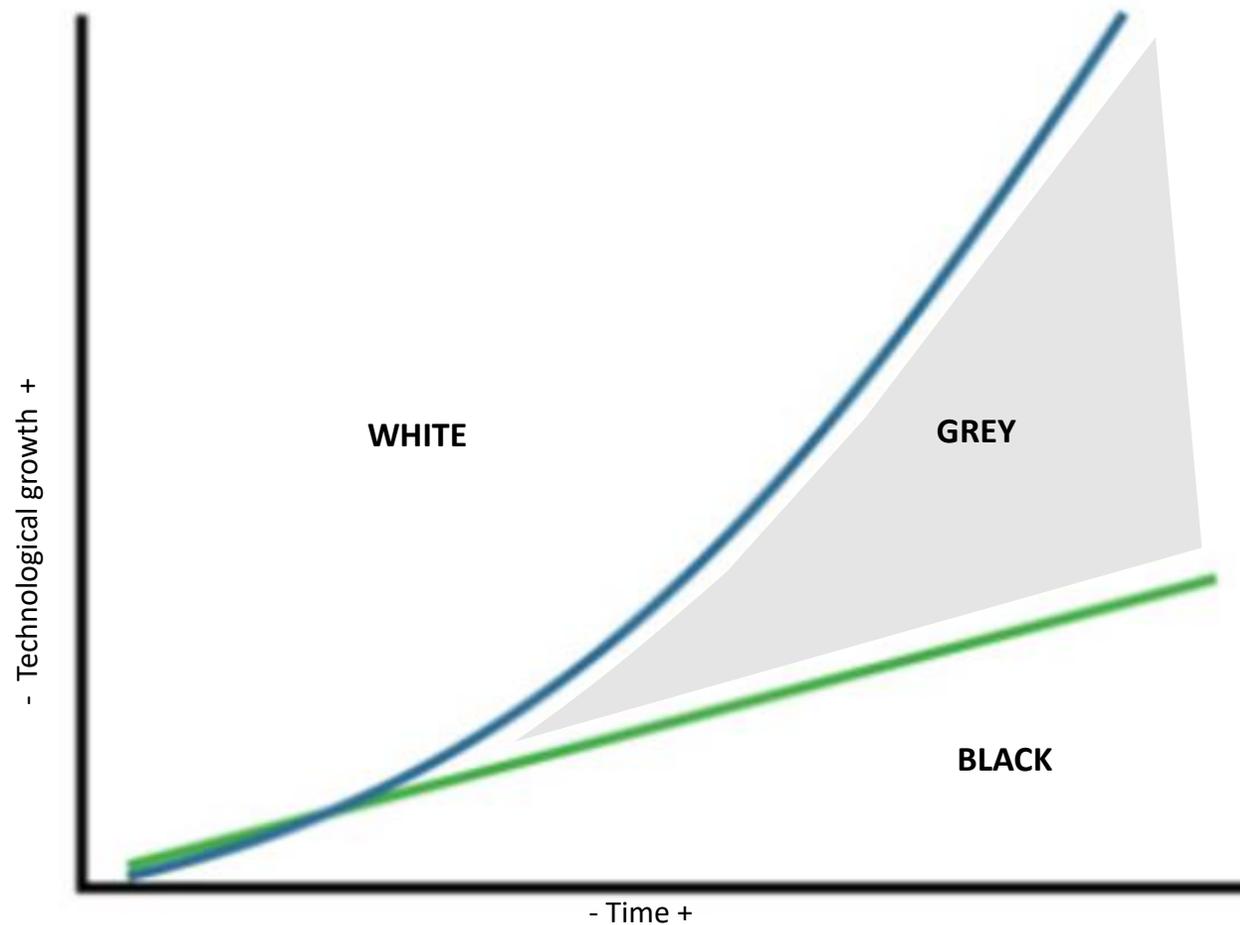


The last 10 years were about Business Ethics The next 10 years will be about Technoethics & Bioethics

- Bioethics & Technoethics
- Algorithmic bias
- Algorithmic safety
- Beneficence of technologies
- Explainability of results
- Transparency & traceability
- Ethicality of decisions
- Auditability
- Diversity, discrimination & fairness
- Data integrity & privacy
- Data portability & interoperability
- Cybersecurity
- Future of work
- Accountability & liability
- Ownership & IP
- Robo-rights
- Dual-use & autonomous weapons
- What else?



Law vs. Technology



- Ethics-by-design
- Co-regulation
- Adaptive risk regulation



Unique opportunity to start working together NOW!

Ethical technologies will:

- ... strengthen APEC trade
- ... foster sustainable economic development
- ... avoid tech scandals and increase reputation
- ... help achieve UHC coverage through health technologies

Next steps:

- ... Expand codes of ethics to include technologies
- ... Collaborate to strengthen technological standards & interoperability
- ... best practice sharing across border



2019 APEC Business Ethics for SMEs Forum

SANTIAGO DE CHILE | 9-10 SEPTEMBER



Thank You!





ETHICAL BUSINESS CONDUCT AND RETURN ON INVESTMENT – WHAT TONE AT THE TOP MEANS FOR SMALL AND MEDIUM ENTERPRISES



Mr. Ken Reali

President and CEO, Clinical Innovations



FOSTERING ETHICAL COLLABORATION BETWEEN HEALTHCARE PROFESSIONALS AND THE MEDICAL DEVICE AND BIOPHARMACEUTICAL INDUSTRIES



Dr. Jeff Blackmer

Vice President for International Health
Canadian Medical Association

Fostering Ethical Collaboration between Healthcare Professionals and the Medical Device and Biopharmaceutical Industries

Dr. Jeff Blackmer
MD MHSc FRCPC CCPE
Vice President, International Health
Canadian Medical Association



ASSOCIATION
MÉDICALE
CANADIENNE



CANADIAN
MEDICAL
ASSOCIATION

Public perception

Wizard of Id



Professional perception (BMJ cover)

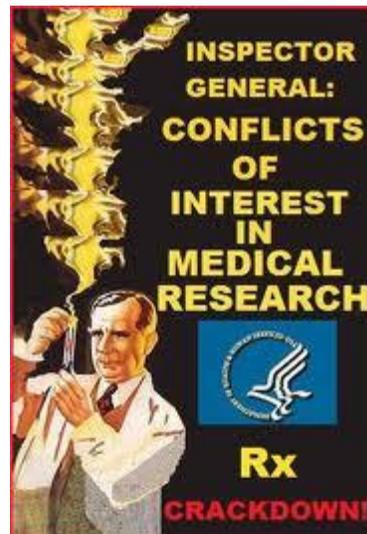


- Yes, we have a problem
- Yes, it still exists

Fundamental ethical principles

- The HCP's first obligation is always the *independent and unbiased* promotion of the health and well being of their patients
- Other interests (e.g. research and publications, academic promotion, financial gain) are legitimate but must be secondary to patient care

- When secondary interests have the potential to influence decisions with respect to patient care, there exists a *conflict of interest*



- Just as physicians have a fiduciary duty to their patients, publicly held companies have a fiduciary duty to their shareholders to maximize profit and return on investment (this is *not* unethical)
- These duties may not necessarily be mutually exclusive – but they are definitely not always mutually inclusive

Bottom line

- In most businesses, companies are able to target consumers directly
- However, consumers can't buy most medications or devices unless they are prescribed or recommended by a HCP
- So, industry targets HCP's to try and convince them to prescribe their drug or use their product

The good

- Important work by organizations like APEC has helped highlight ethical challenges and foster important conversations
- Codes of Conduct assist in setting standards and may be useful in ethical decision making

The bad

- There is not always consistency between Codes and organizational or professional culture/actual behavior
- Interests and incentives for the various parties involved are not always aligned and sometimes are diametrically opposed

The ugly

“The bottom line is that if you don’t pay off the doctors, you will not succeed in pharmaceutical sales. Period.”

Jordan Katz, former US rep for Schering-Plough



“There is a big bucket of money sitting in every physician’s office. Every time you go in, you reach your hand in the bucket and grab a handful.”

Mike Zubillaga, Astra Zeneca marketing director in an internal memo, subsequently fired

“Anytime we had a paid relationship with a physician they increased their use of our drug. I hate to say it out loud, but it all comes down to ways to manipulate the doctors.”

Kathleen Slattery, former sales rep for Bristol Myers Squibb

Codes vs. Culture

- Are any of these quotes in any way consistent with current professional Codes, policies or internal standards?
- If not – how do we make sure the work being done here leads to a different outcome? How do we align Codes with Culture?

Challenges

- Find a way to consistently reconcile the (often competing) duties and fundamental professional obligations held by HCP's and for-profit companies
- Facilitate genuine collaboration to achieve common goals

Opportunities

- In addition to development of Codes, address fundamental organizational culture
- Find a way to align goals and incentives between HCP's and companies/their representatives
- For companies: Do well *and* do good

NYT August 20, 2019

Shareholder Value Is No Longer Everything, Top C.E.O.s Say

Chief executives from the Business Roundtable, including the leaders of Apple and JPMorgan Chase, argued that companies must also invest in employees and deliver value to customers.



Chief executives who are members of the Business Roundtable, include, left to right, front row: Julie Sweet of Accenture North America, Brian Moynihan of Bank of America, Tim Cook of Apple, Robert F. Smith of Vista Equity Partners of Austin. Back row: Jeff Bezos of Amazon, Mary Barra of General Motors and Larry Fink of BlackRock.

Left to right, Greg Kahn for The New York Times, Arnd Wiegmann/Reuters, Bebetto Matthews/Associated Press, Chester Higgins Jr./The New York Times, Patrick Semansky/Associated Press, Mike Cohen for The New York Times and Damon Winter/The New York Times.

By David Gelles and David Yaffe-Bellany

Aug. 19, 2019

Nearly 200 chief executives, including the leaders of Apple, Pepsi and Walmart, tried on Monday to redefine the role of business in society — and how companies are perceived by an increasingly skeptical public.

- *Breaking with decades of long-held corporate orthodoxy, the Business Roundtable issued a statement on “the purpose of a corporation,” arguing that companies should no longer advance only the interests of shareholders.*

- *Businesses are pledging to fight climate change, reduce income inequality and **improve public health**.*
- *It is an explicit rebuke of the notion that the role of the corporation is to maximize profits at all costs — the philosophy that has held sway on Wall Street and in the boardroom for 50 years.*

This could create a unique (and bold) opportunity

- Realign internal culture and expectations away from profit maximization/shareholder returns and towards optimization of individual and public health
- Realign incentive programs away from profit and increased use of medications/devices and towards overall health outcomes for a condition or procedure

Ultimate Challenge

- Better align the interests and fiduciary obligations of HCP's and industry
- **Suggested end goal:** That HCP's and drug and device manufacturers develop policies and procedures that will incentivize and promote the use of the *right* drug or device at the right time for that particular patient in order to optimize patient outcomes *without* profit considerations

Current state



Desired future state





LUNCH

PEDRO DE VALDIVIA ROOM

(DOWNSTAIRS)

12:00 – 13:00



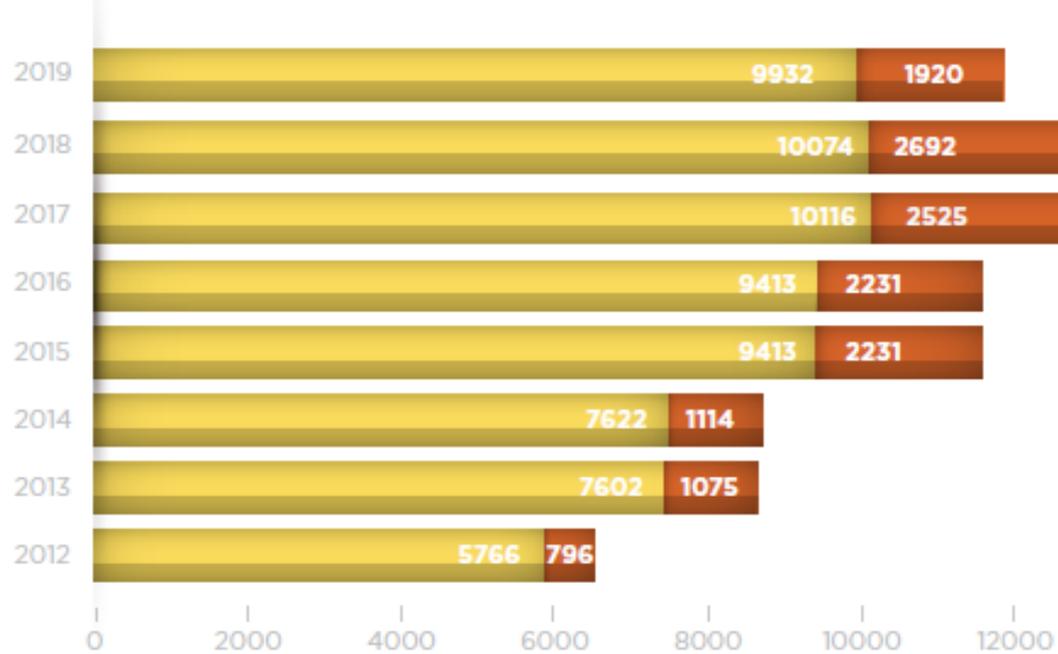
INDUSTRY ASSESSMENT:
PROGRESS, CHALLENGES, AND
RECOMMENDATIONS FOR THE REGION &
SESSION ON STRATEGIES TO MEASURE THE
POSITIVE IMPACT OF ETHICAL PRACTICES

*Ms. Nancy Travis, Vice President,
International Compliance and Governances,
The Advanced Medical Technology
Association (AdvaMed)*



2019 Survey Results: Code Adoption

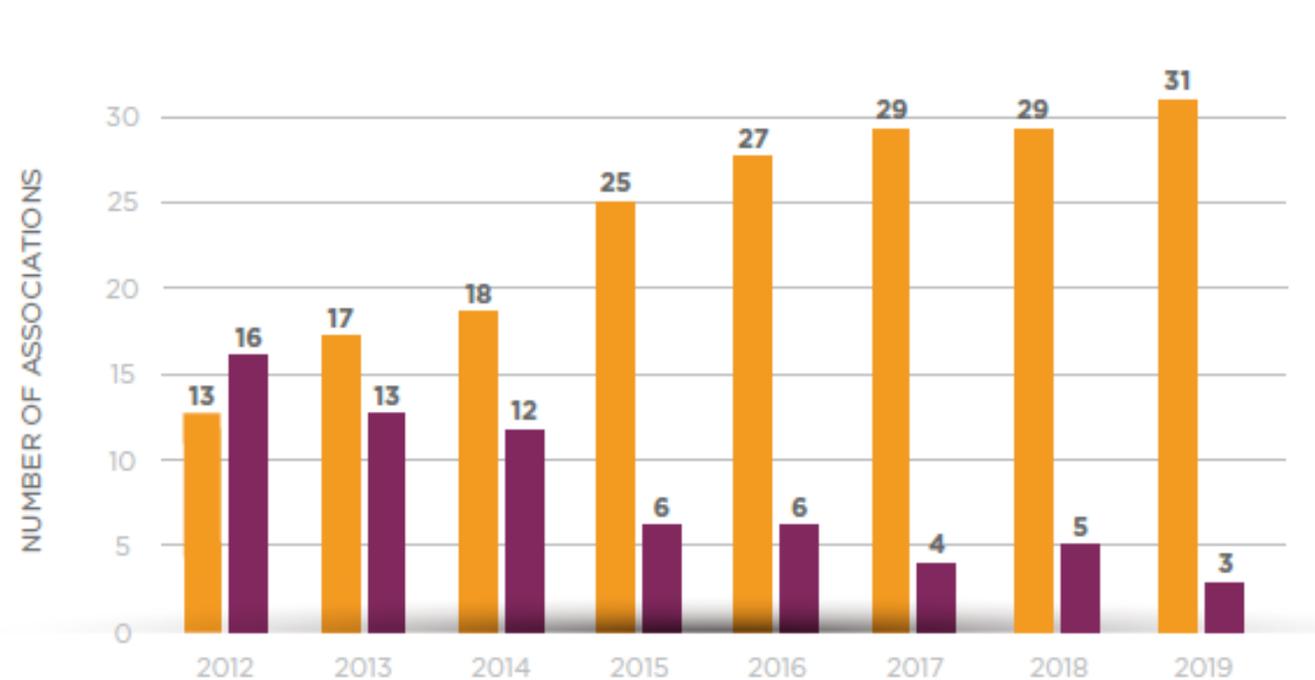
ENTERPRISE MEMBERSHIP OF ASSOCIATIONS WHO HAVE ADOPTED A CODE OR CODE COMMITMENT



NUMBER OF MEMBER ENTERPRISES

SME MEMBERS IN ASSOCIATIONS WITH A CODE OR CODE COMMITMENT
 ASSOCIATIONS WITHOUT A CODE OR CODE COMMITMENT

INDUSTRY ASSOCIATIONS WITH A CODE OR CODE COMMITMENT



ASSOCIATIONS WITH A CODE OR CODE COMMITMENT
 ASSOCIATIONS WITHOUT A CODE OR CODE COMMITMENT



2019 Survey Results: Code Implementation

CODE GOVERNANCE

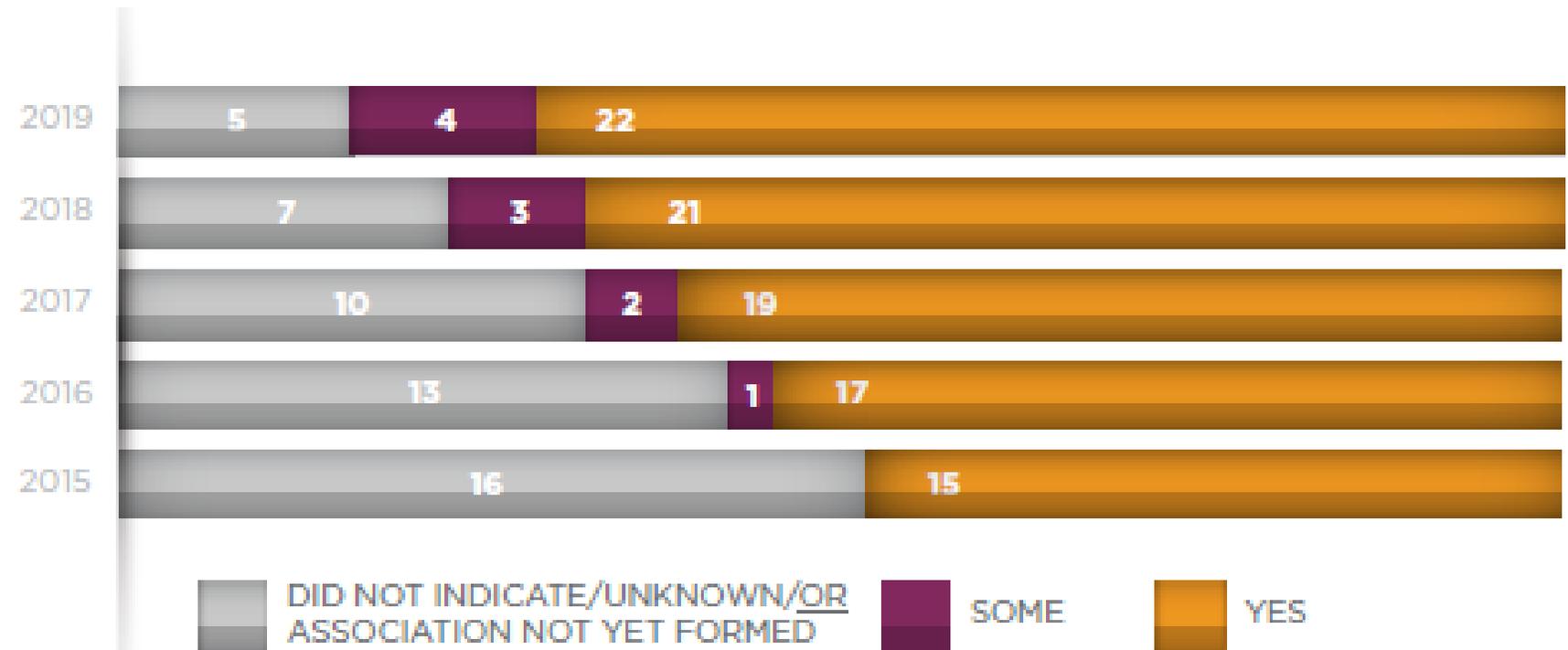
Code Governance Indicator	Percent “Yes” in 2019
Provide one-on-one assistance to members on the code	91%
Distributed the code to all members within the last two years	77%
Procedures in place to review the code and ensure it is up-to-date	64%
Offering ethics training for third party intermediaries	41%
Sufficient resources to support code activities	41%
Offering ethics training to individual sales representatives	36%
Code compliant or violation procedure	32%



2019 Survey Results: Code Implementation

CODE ALIGNMENT

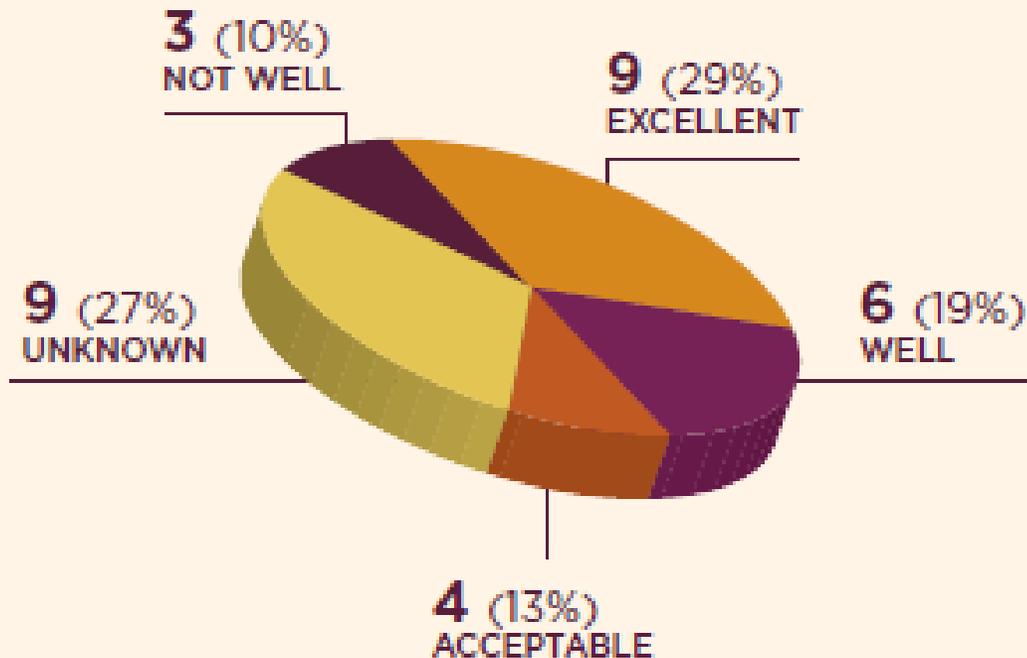
REPORTED EMBRACE OF THE FIVE FUNDAMENTAL PRINCIPLES OF THE APEC KUALA LUMPUR PRINCIPLES BY ASSOCIATIONS WITH A CODE OR CODE COMMITMENT:



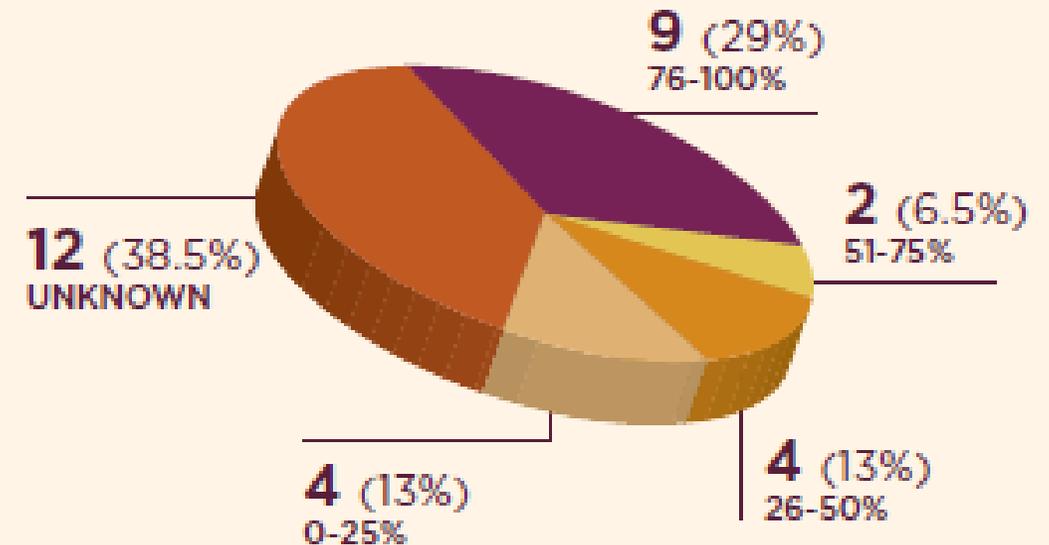


2019 Survey Results: Code Implementation MEMBER COMPANY ADHERENCE

SELF-ASSESSMENT ON CODE PERFORMANCE BY
31 ASSOCIATIONS WITH A CODE / COMMITMENT



MEMBER IMPLEMENTATION RATE BY
31 ASSOCIATIONS WITH A CODE / COMMITMENT





2019 Survey Results: Code Implementation

EXTERNAL ENGAGEMENT

Interest to Heighten
External Stakeholder
Engagement:

76%

yes

Associations reporting that
they have distributed the code
to non-members:

38%

Associations building awareness
for code of ethics with non-members
through formalized collaborations
such as consensus frameworks: :

48%



Thoughts on Strategies to Measure the Positive Impact of Ethical Practices

1. **AdvaMed has particular interest in assessing the positive impact of ethical practices on business success, particularly for SMEs, and innovation.**
2. **We would also support measuring the positive impact of ethical business practices on other areas, including the economy and public health.**
3. **APEC has led consortiums on research before and could do so again**
4. **The approach should be scaled over time, perhaps with a narrow scope in the first phase and expanded scope after initial results are demonstrated**



INDUSTRY ASSESSMENT: PROGRESS, CHALLENGES, AND RECOMMENDATIONS FOR THE REGION AND STRATEGIES TO MEASURE THE POSITIVE IMPACT OF ETHICAL PRACTICES



Mr. Thomas Cueni

Director General, International Federation of
Pharmaceutical Manufacturers and Associations

Industry Co-Chair, APEC Biopharmaceutical
Working Group on Ethics



2019 Survey Results: Code Adoption

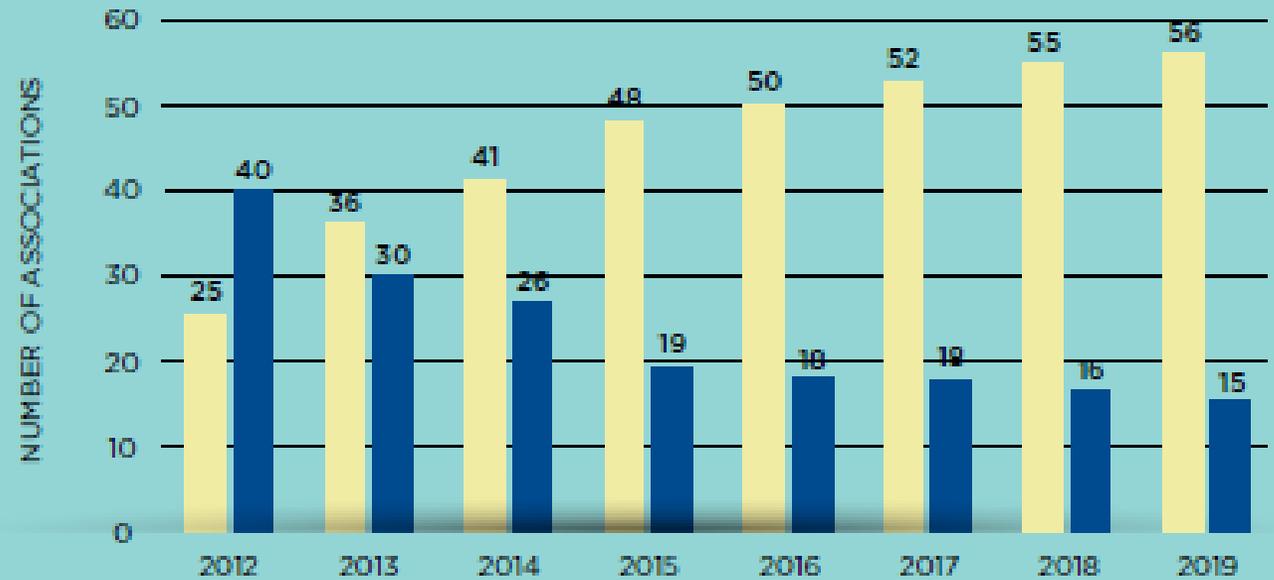
COMPANY MEMBERSHIP IN ASSOCIATIONS WITH A CODE OF ETHICS OR CODE COMMITMENT



NUMBER OF MEMBER ENTERPRISES IN ASSOCIATIONS WITH A CODE

■ SME MEMBERS
 ■ LARGE MEMBERS

INDUSTRY ASSOCIATIONS WITH A CODE OR CODE COMMITMENT



■ ASSOCIATIONS WITH A CODE OR CODE COMMITMENT

■ ASSOCIATIONS WITHOUT A CODE OR CODE COMMITMENT



2019 Survey Results: Code Implementation

CODE GOVERNANCE

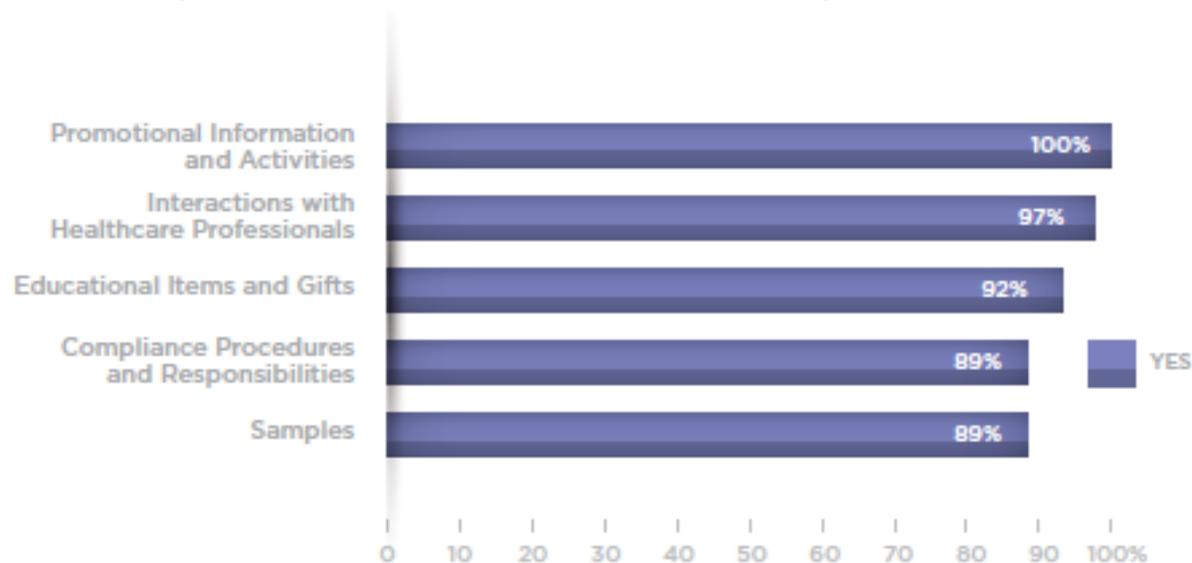
Code Governance Indicator	Percent “Yes” in 2019
Distributed the code to members for input before adoption	97%
Distributed the code to all members within the last two years	95%
Designated staff or a member to oversee code activities	89%
Procedures in place to review the code and ensure it is up-to-date	87%
Sufficient resources to support code activities	87%
Code compliant or violation procedure	87%
Provide one-on-one assistance to members on the code	70%
Offer one or more code trainings to members per year	65%



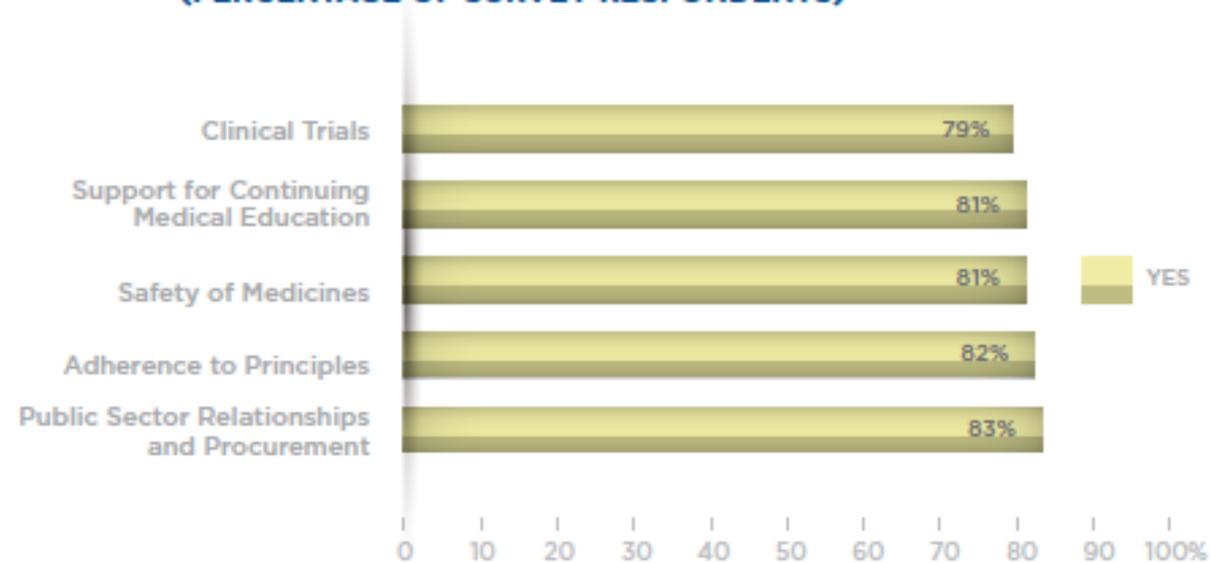
2019 Survey Results: Code Implementation

CODE ALIGNMENT

TOP 5 PROVISIONS OF THE APEC MEXICO CITY PRINCIPLES ALIGNED WITH INDUSTRY ASSOCIATION CODES OF ETHICS (PERCENTAGE OF SURVEY RESPONDENTS)

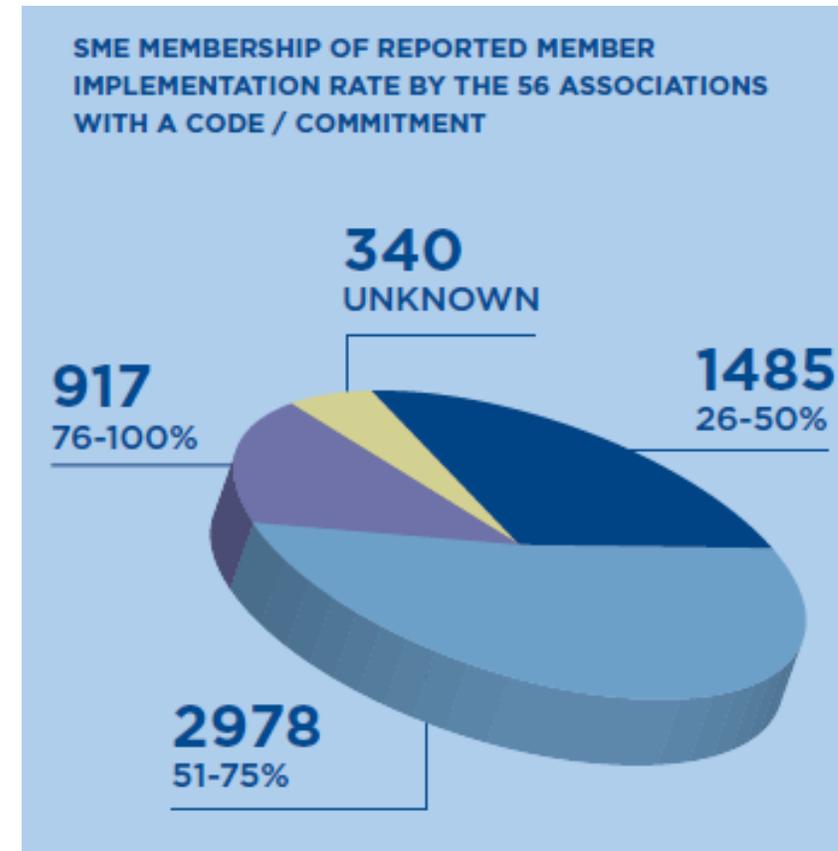
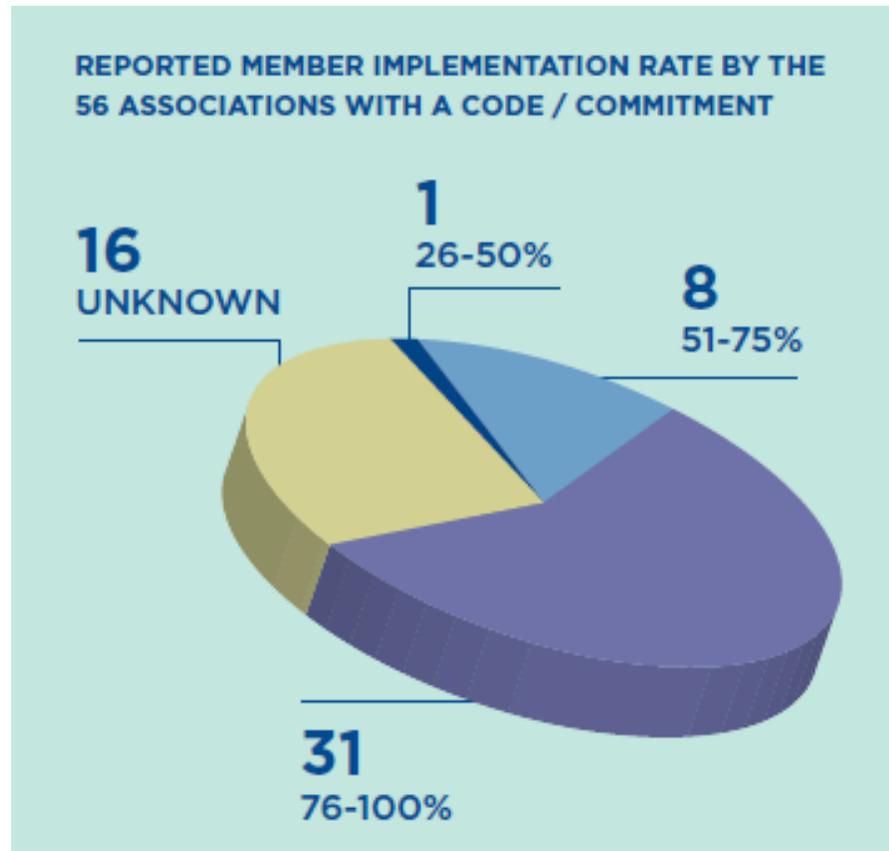


LOWEST 5 PROVISIONS OF THE APEC MEXICO CITY PRINCIPLES ALIGNED WITH INDUSTRY ASSOCIATION CODES OF ETHICS (PERCENTAGE OF SURVEY RESPONDENTS)





2019 Survey Results: Code Implementation MEMBER COMPANY ADHERENCE

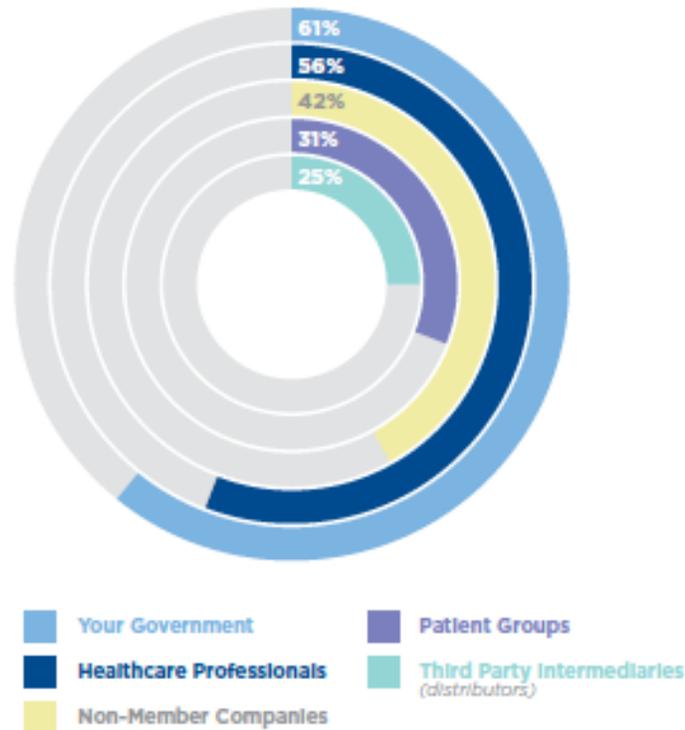




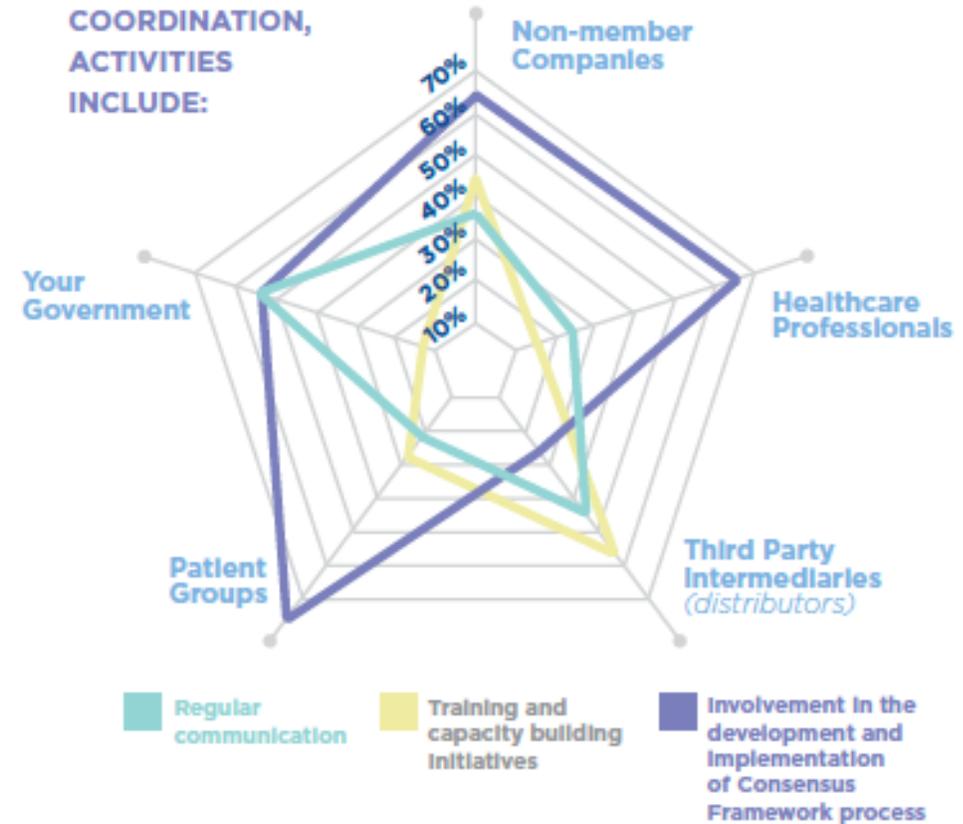
2019 Survey Results: Code Implementation

EXTERNAL ENGAGEMENT

COORDINATION WITH NON-MEMBER STAKEHOLDERS ON ETHICAL PRACTICES AND/OR YOUR CODE OF ETHICS



IF THERE IS COORDINATION, ACTIVITIES INCLUDE:





Biopharmaceutical Industry Associations: Greatest Opportunities

Reducing Costs
Communication **Low Complaints**
High-Standard Alignment
Member Adherence
Culture of Integrity **Training**
Leadership Commitment
Member Engagement
Collective Action across Industry
Stakeholder Engagement



Biopharmaceutical Industry Associations: Greatest Challenges

Communication
Member Divergence
Resources Multiple Codes
Member Adherence
Code Implementation
Stakeholder Engagement
Non-member Dilemma
Member Awareness
Collective Action
Training Complaint Proceedings



Thoughts on Strategies to Measure the Positive Impact of Ethical Practices

1. Focus on positive impact of ethical business practices on our economies, businesses, health systems, and/or innovation.
2. We may want to pick one or two specific areas and start there.
3. Quality research is paramount and this may take time.
4. Strategy should include diversity in approach, with contributions from both side of the Pacific and both developed and developing economies.



GOVERNMENT STRATEGIES TO ENCOURAGE ETHICAL BUSINESS CONDUCT

- Convening Power
- Procurement
- Regulatory Practices
- Enforcement Recognitions and Incentives
- Government Supported Business Ethics Training
- Trade Agreements



GOVERNMENT STRATEGIES TO ENCOURAGE ETHICAL BUSINESS CONDUCT



Ms. Claudia Ortega Forner
Public Prosecutor's Office, Chile



Mr. Ricardo Miranda Zúñiga
Legal Advisor, ChileCompra



Ms. Sabrina Chan
Senior Executive Director, Hong
Kong Association of the
Pharmaceutical Industry

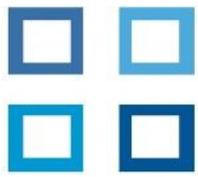


Ms. Faye Sumner
Chief Executive Officer, Medical
Technology Association of New
Zealand (MTANZ)



GOVERNMENT STRATEGIES TO ENCOURAGE ETHICAL BUSINESS CONDUCT

- Convening Power
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- Government Supported Business Ethics Training
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medical technology
ASSOCIATION OF NEW ZEALAND



This certifies that

EDWARDS LIFESCIENCES NZ LTD

is a member of the Medical Technology Association of New Zealand

31 March 2020

For the year ending

609028

Membership Number

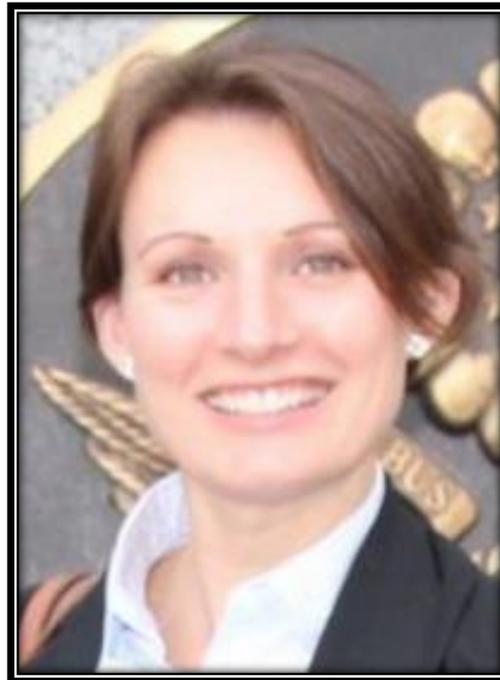
Faye Sumner CNZM, Chief Executive



AFTERNOON TEA / COFFEE BREAK (OUTSIDE SAN CRISTOBAL ROOM) 14:45 – 15:00



PLENARY SESSION



THE FUTURE OF THE NANJING DECLARATION

Ms. Tricia Van Orden, Overseer, Business Ethics for APEC SMEs Initiative



Business Ethics for APEC SMEs Initiative: Medical Device & Biopharmaceutical Sectors

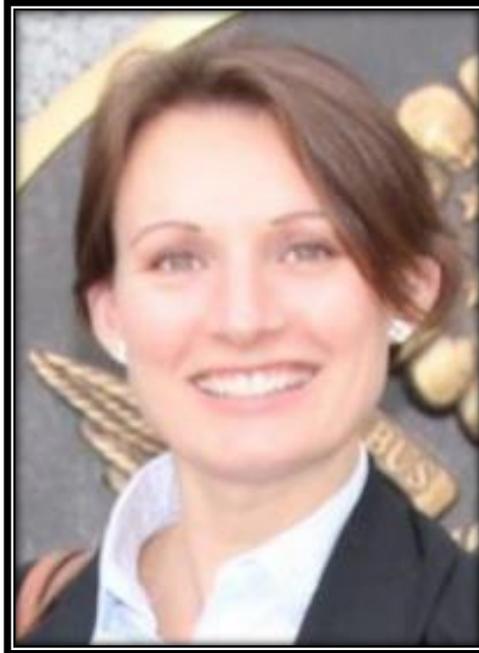
Strategic Assessment of 2020 Commitments

Updated August 2019

INPUTS <i>Who Provides What</i>	ACTIVITIES <i>What We Do Together</i>	OUTPUTS <i>The Products of Our Work</i>	OUTCOMES <i>The Changes from these Products (Quantifiable)</i>	IMPACT <i>The Benefits from these Changes</i>
<ul style="list-style-type: none"> Industry (SMEs): Commitment to engage directly with the initiative and local industry associations to strengthen their own capacity Industry (Large Enterprises): Commitment to engage directly with the initiative and local industry associations to strengthen their own capacity and to lend resources (expertise, financial, or otherwise) Industry (Associations): Commitment to engage directly with the initiative and their members to strengthen the capacity of enterprises within their economy and to lend resources (expertise, financial, or otherwise) Industry (Third Parties – Distributors, Marketers, etc.): Commitment to engage directly with the initiative and local industry associations to strengthen their own capacity Governments: Commitment to serve as partners and foster regulatory environments that encourage ethical conduct and lend resources where appropriate (expertise, financial, or otherwise) Healthcare Professionals / Healthcare Providers: Commitment to engage directly with the initiative at all levels to build capacity, align practices, and lend resources (expertise, financial, or otherwise) Patients: Commitment to provide all stakeholders with routine inputs and to advocate for APEC Principles 	<ul style="list-style-type: none"> Setting Best Practices: Identify, align, and endorse the highest standard ethical business practices across all member economies. Capacity-Building: Facilitate adoption and implementation of the highest standard ethical business practices by all industry and non-industry actors relevant to both sectors, supporting opportunities between and within member economies. Monitoring and Evaluation: Setting indicators to quantify progress in the adoption and implementation of high standard ethical business practices across all member economies, while actively monitoring this process to determine changes over time and evaluating results. 	<p>APEC Kuala Lumpur Principles & APEC Mexico City Principles / Model Industry Association Code of Ethics</p> <p>APEC Nusa Dua Statement and APEC Nanjing Declaration</p> <p>Ethics Experts Network (Both Sectors)</p> <p>APEC Business Ethics for SMEs Forum</p> <p>APEC Biopharmaceutical Working Group</p> <p>APEC Guide to Facilitate Multi-Stakeholder Ethical Collaborations (Consensus Frameworks)</p> <p>Industry Code Compendiums (Both Sectors)</p> <p>APEC Guidance for Ethical Third Party Intermediary Relationships in the Medical Device Sector + Tokyo Action Agenda Recommendations (2018-2021)</p> <p>Lighthouse Award</p> <p>Surveys/Reports on Code of Ethics Implementation by APEC Industry Associations (Both Sectors)</p> <p>Programs to Scale Capacity-Building for SME Implementation of the APEC Principles</p> <ul style="list-style-type: none"> APEC SME Leaders in Ethics and Integrity Program (LEIP) Distributor Ethics Toolkit and Compliance Capacity-Building Portal (Medical Device Sector) <p>Resource Guide: Government Strategies to Encourage Ethical Business Conduct</p> <p>Patient Organizations' Ethics Network and Toolkit to support implementation of the APEC Principles / Consensus Frameworks</p>	<p>Achievements To Date:</p> <ul style="list-style-type: none"> Recognition and support to strengthen ethical business practices by APEC Economic Leaders and Ministers Expand the total number of industry association codes of ethics or code commitments in both sectors from 38 (2012) to 84 (2019), more than doubling the number across APEC – including in 10 APEC economies for the first time – and extending best practices to nearly 20,000 enterprises. Improved code implementation by industry associations across a range of indicators, including improved governance, alignment with best practices, member adherence, and external engagement (see 2019 APEC Reports for further details on indicators). Adoption of “Consensus Framework” agreements for multi-stakeholder ethical collaboration in nine APEC economies (Australia, Canada, Chile, China, Japan, Mexico, Peru, The Philippines, Viet Nam) with others under development, formally bringing together more than 150 leading health organizations under a common approach to strengthen ethical conduct. From 2012-2018, in-person “train-the-trainer” capacity-building sessions for over 1,500 senior leaders from every stakeholder and every APEC economy. <p>Achievements in Progress:</p> <ul style="list-style-type: none"> Universal industry association code adoption by 2020 and positive indication that, among those industry associations with a code, the majority of their member enterprises adhere to its provisions in their daily business practices. Adoption of “Consensus Framework” agreements in all remaining APEC economies as well as the identification of new success indicators in the implementation of these agreements. Realization of the Tokyo Action Agenda Recommendations (Goals) 	<ul style="list-style-type: none"> Economic: Strengthen growth and cross-border trade, competitiveness; reduce public waste and regulatory / enforcement burden. Business: Strengthen domestic and cross-border market access for SMEs, facilitate fair competition in the marketplace, improve productivity; reduce reputational and legal costs. Social: Strengthen health system outcomes for patients, public confidence/trust in healthcare system, access to life saving and enhancing products, and expand local innovation capabilities. Innovation: Strengthen trust between stakeholders that is necessary to expedite the discovery or improvement of new products and processes, while strengthening confidence in investment.



PLENARY SESSION



CLOSING SUMMATION AND LOOKING AHEAD

Ms. Tricia Van Orden, Overseer, Business Ethics for APEC SMEs Initiative