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Briefing Paper

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A hope fulfilled

Malaysia's journey to curing hepatitis C

By overriding a pharmaceutical giant's monopoly and collaborating in the development of a breakthrough new treatment, Malaysia is on its way to ending the deadly scourge of hepatitis C.

Karina Yong

Huang[1] gazes into the distance, joy and contentment gently beaming from his face. After 12 years of waiting, he has finally been cured of hepatitis C. Until recently, the prognosis of hepatitis C virus (HCV) was a death sentence to many. Untreated, HCV can lead to liver disease, cirrhosis, cancer and, finally, death.

HCV in Malaysia

Malaysia's journey towards achieving the World Health Organization (WHO)'s 2030 elimination targets for HCV is nothing short of a dream come true. In 2017, it became the first country to issue a compulsory licence for HCV treatment in order that more affordable generic medicines could be brought in to treat her people. Malaysia achieved another milestone when on 4 June 2021, she became the first developing country to register a new treatment for HCV locally, achieved through a collaboration driven by 'values, love, trust and justice' rather than profits.

Malaysia has more than 400,000 people suffering from HCV. The disease is a global public health concern. Worldwide HCV affects about 58 million people, with only 13% of that population receiving treatment to date. HCV has a death toll of 300,000 yearly.[2] There are five main strains of the hepatitis virus (A to E). Hepatitis B and C can lead to death.

HCV is a blood-borne virus and can be caught through exposure to contaminated blood such as through the sharing of needles and other injection equipment; the reuse or inadequate sterilisation of medical equipment; transfusion of unscreened blood and blood products; and sexual practices that can lead to exposure to blood.[3] HCV affects the liver primarily, causing inflammation. In the long run, if the process of inflammation

1 Huang Siang Ping, a farmer in Penang, Malaysia. Watch his story here: https://www.youtube.com/watch?v=vG_IH7OYJsE

2 https://dndi.org/press-releases/2021/first-hepatitis-c-treatment-developed-through-south-south-cooperation-registered-in-malaysia/

3 https://www.who.int/malaysia/news/detail/28-07-2020-hepatitis-c-in-malaysia-from-crisis-to-hope

Third World Network (TWN) is an independent non-profit international research and advocacy organisation involved in bringing about a greater articulation of the needs, aspirations and rights of the peoples in the South and in promoting just, equitable and ecological development.

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is not stopped, 70% of those infected will end up developing chronic hepatitis C, with 15-20% of them then developing liver disease, cirrhosis and cancer.[4] At present, there is no replacement therapy for livers nor any machines which can replace the functions of a liver, making the early treatment of HCV crucial. Although HCV is easily diagnosed using a rapid diagnostic finger prick test (RDT), it is known as a 'silent killer' as many patients are asymptomatic until later stages, when symptoms arise from liver damage.

Dr Muhammad Radzi Abu Hassan, the National Head of Gastroenterology and Hepatology in the Malaysian Ministry of Health (MOH) who has been a clinician for 30 years, has recounted how the diagnosis of HCV was a death sentence in the past. Without treatment, doctors watched patients die. In the late 1980s or the 1990s, interferon-based treatment regimens were introduced. These treatments are, however, complex to administer. One requires a weekly interferon injection with daily ribavirin tablets for a duration of about six months. Toxic side-effects include fatigue, depression, alopecia, the development of thyroid disease and even suicidal thoughts. Cure rates are also low, averaging around 40-45%.[5] Mr Huang had been put on the interferon regime but was told after five months that he had not responded positively to the treatment and the disease was still in his body. It was a long 12-year wait before he was healed with ravidasvir, a direct acting antiviral (DAA) in the development of which Malaysia played a large part.

The DAA journey

DAAs marked a breakthrough in the treatment of HCV. Making their debut in 2015, these are tablet treatments that can cure patients in as little as eight weeks. These new treatments have short durations, minimal side-effects and efficacy approaching 90-100%.[6] DAAs eliminate HCV from the body by preventing the multiplication of the virus.

Many of the new treatment regimens are, however, dependent on a base drug known as sofosbuvir, which is produced by the multinational pharmaceutical company Gilead Sciences and patented in Malaysia. Patents grant Gilead a monopoly over the marketing of sofosbuvir and Gilead's original asking price was $84,000 for 12 weeks of treatment.[7] This resulted in widespread backlash from governments, patients and international health organisations. In Malaysia, Gilead was granted patents for the sofosbuvir compounds family and a prodrug, leading to a monopoly of the market until 2028. Due to the high cost, the government was unable to include the new DAAs in the public health system and could only treat 640 persons a year for HCV.[8]

Patents over pharmaceutical (and other) products were introduced into Malaysian law when the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) came into effect in Malaysia in January 1995. This agreement sets international minimum standards for the regulation of intellectual property for its members, and patents must be given for both products and processes for a minimum term of 20 years. The TRIPS Agreement has become a big setback to the growth of a vibrant pharmaceutical manufacturing sector and it has also created a lot of the barriers to access to medicines.

Nevertheless, it does still leave considerable policy space for national laws to determine the exact level of intellectual property protection. Intellectual property rights (IPRs) are private rights and cannot trump matters of public importance. For this reason, the WTO Ministerial Conference in 2001 adopted the Doha Declaration which recognises the effect that patents can have on pharmaceutical prices and states as follows: 'We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.' It further recognises that patent rights can be overriden by the issuance of what are known as compulsory licences where there is a national emergency or extreme urgency. Despite the above, however, the battle for the recognition of the right to health and affordable and accessible medicines has been an uphill one.

4 https://www.who.int/news-room/fact-sheets/detail/hepatitis-c
5 https://www.moh.gov.my/moh/resources/Penerbitan/Laporan/Umum/CaseStudy-HEPATITIS.pdf
6 Ibid.
7 In comparison, it is estimated that the drug can be produced at $171-360 for 12 weeks of treatment.
8 https://www.mac.org.my/v3/wp-content/uploads/2017/07/HCV_Report_A4_FA_23052017-web.pdf

Malaysia has not incorporated in her laws the full measure of flexibilities allowed by the TRIPS Agreement. For example, Malaysia granted patents on sofosbuvir when the same were rejected in Egypt as Malaysia's patenting standards on novelty and inventiveness are less stringent than Egypt's. The Malaysian law on patents and the patent examination procedures at the Malaysian Intellectual Property Office (MyIPO) can be tightened to ensure that they do not undermine public health. The COVID-19 pandemic has underscored the need for robust public health systems and independent local pharmaceutical industries. Local production capacity and expertise must be developed to meet current and future needs.[9]

As Chee Yoke Ling, executive director of the Third World Network (TWN), points out: '[T]he journey for many policy and [civil society] organisations locally and globally since 2001, is to make sure our national intellectual property laws serve public interest, public health, independent development of our local industry so that we do not have to depend on imports from the West...'

Data and know-how distinguish the developed from the developing countries and inappropriately designed intellectual property right regimes serve to widen the gap. When it comes to IPRs, one size does not fit all. Differentiation of terms based on the stage of development that each country finds itself in is crucial, especially in light of growing evidence that stronger IPR regimes do not in fact encourage an increase in innovation but rather the opposite.[10]

Faced with the high prices of sofosbuvir against a commitment to heal her people and eradicate HCV by 2030, Malaysia issued a government use licence (GUL) in September 2017. A GUL is a form of compulsory licence issued by the government under Section 84 of the Malaysian Patents Act.[11] The decision to issue the compulsory licence was made after more than two years of unsuccessful negotiations with Gilead for Malaysia's inclusion in the company's voluntary licensing arrangements[12] and also to reach a price that was affordable to the Malaysian MOH for scaling up treatment. Prior to the negotiations, the Malaysian government had carried out research and analysis on treatment options using generic medicines, prices of generic medicines in other countries where there were no intellectual property barriers, the intellectual property situation in Malaysia and the government's responsibility to provide treatment and healthcare.

MOH led the initiative for the issuance of a government use compulsory licence. It worked with officials in the Ministry of Domestic Trade and MyIPO as well as the Ministry of International Trade and Investment. MOH officials also received technical inputs from domestic experts. Finally, it provided all the data and analysis to support the use of a GUL and presented a working paper to the Malaysian Cabinet, which approved the request of MOH in early August 2017.

In the following month, Malaysia publicly confirmed the issuance of the GUL for the importation of generic sofosbuvir from Pharco Pharmaceuticals, an Egyptian manufacturer. Meanwhile, having caught wind of the intended issuance of the GUL, Gilead announced through Twitter in late August that Malaysia, Thailand, Ukraine and Belarus would be included in the geographical scope of its voluntary licence with Indian manufacturers. The Malaysian government examined the implications of each option and decided to proceed with the government use licence. Gilead's recommended price for governments for sofosbuvir is $750 for

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9 https://unctad.org/news/covid-19-heightens-need-pharmaceutical-production-poor-countries

10 https://www.econstor.eu/bitstream/10419/89516/1/771928769.pdf

11 Section 84(1) of the Patents Act titled 'Rights of Government' provides an important remedy for the government where a patent owner or his licensee behaves in an anti-competitive manner, or 'where there is national emergency or where the public interest, in particular, national security, nutrition, health or the development of other vital sectors of the national economy as determined by the Government, so requires'. In any of these circumstances, the Minister of Domestic Trade, Cooperatives and Consumerism can, without the agreement of the patent owner, designate a government agency or a third party to work the patent. As allowed in the TRIPS Agreement for 'public non-commercial use', Malaysia's government use provision does not require the government to try and negotiate with the patent owner for a voluntary licence before issuing the 'government use' order. The patent owner shall be notified of the Minister's decision 'as soon as is reasonably practicable'. Section 84(3) provides for 'the payment to the owner of the patent of an adequate remuneration'. The Rights of Government provision is limited to predominantly supplying the market in Malaysia.

12 The Gilead voluntary licence excluded many middle-income countries including Malaysia, Thailand, China, Brazil and South Africa.

12 weeks of supply. Under the GUL, the supply of generic sofosbuvir (400 mg tablet) had a capped price of around $40 for a month of supply.[13]

Following the issuance of the GUL, Malaysia rolled out generic sofosbuvir/daclatasvir treatment. In Malaysia, there is no patent on daclatasvir. The cost of the generic sofosbuvir/daclatasvir treatment is less than RM1,200 ($300) for a three-month course, allowing the government to provide free hepatitis C treatment to patients nationwide.

In 2017 then, there were both the GUL and Gilead's voluntary licence operating in Malaysia in terms of supply of DAAs. The options for Malaysia were as follows:

- Import of generic sofosbuvir from Egypt under the GUL (for public hospitals only);
- Import of generic daclatasvir (for both public and private facilities);
- Import of Gilead-licensed generics from voluntary licence holders in India where these companies register their products in Malaysia: sofosbuvir, sofosbuvir/daclatasvir, sofosbuvir/velpatasvir (for public and private facilities).

Malaysia's step of issuing a GUL was a very bold one. Although it is expressly allowed by the TRIPS Agreement, developing countries very rarely issue compulsory licences for fear of repercussions from the West. This was only the second time Malaysia had issued a compulsory licence in spite of the fact that many drugs, for example, those for the treatment of cancer, are too expensive to be put on MOH's national essential medicines list. Malaysia's first compulsory licence was issued in 2003 for HIV treatment. The GUL for sofosbuvir was widely celebrated internationally amongst health officials, patient groups and civil society organisations.[14] In comparison, Gilead and its political allies responded with pressure in an attempt to obtain a reversal of the issuance of the GUL.[15]

Malaysia has now gone a step further in the HCV journey. On 4 June 2021, it celebrated an incredible milestone. It became the first South country to register a new treatment for HCV, known as ravidasvir. More than that, the journey expanded along the way to embrace a full access and treatment strategy in a firm commitment to saving lives through eliminating HCV.

Newly manufactured by Pharco, ravidasvir is a pan-genotypic treatment. In 2017, Malaysia participated in clinical trials to test ravidasvir. Pharco had agreed to set the price of the combination treatment (using ravidasvir and generic sofosbuvir) at $300 per 12-week course upon registration. This would benefit not only the public but also the private sector. Before ravidasvir, a full course of treatment in the private sector cost around $70,000. More importantly, the success of the ravisdavir trial would mean affordable life-saving treatment for HCV patients around the world.

The Drugs for Neglected Diseases initiative (DNDi), an international non-profit organisation working to get treatment for neglected patients, had discovered ravidasvir while studying the DAA landscape. It found that Pharco had done a clinical trial using ravidasvir with very promising results. Following that discovery, DNDi, with the ministries of health of Malaysia and Thailand, conducted a clinical trial on the safety and efficacy of ravidasvir, known as STORM-C. In results published in April 2021 in *The Lancet Gastroenterology & Hepatology*, the combination showed cure rates of 97% and was well tolerated in a diverse adult population with chronic HCV infection, even by those infected with genotype 3 of the virus, which is particularly hard to treat. Further, there are no clinically significant interactions between ravidasvir and the antiretrovirals commonly used to treat HIV, making the new combination particularly useful to clinicians.[16] The collaboration

13 https://apps.who.int/iris/bitstream/handle/10665/260445/WHO-CDS-HIV-18.4-eng.pdf?sequence=1

14 https://www.thestar.com.my/news/nation/2018/01/19/malaysia-awarded-for-gutsy-move-govt-invokes-compulsory-licensing-for-affordable-hepatitis-c-medicin

15 https://msfaccess.org/malaysias-compulsory-license-sofosbuvir-positive-step-public-health-and-innovation

16 https://dndi.org/press-releases/2021/first-hepatitis-c-treatment-developed-through-south-south-cooperation-registered-in-malaysia/

was also supported in funding by the international medical humanitarian organisation Medecins Sans Frontieres.

Ravidasvir is thus the very first drug for HCV to be developed in the South with funding and clinical support from non-profit organisations, a private-public partnership. Pharco and DNDi then partnered with Malaysian drug manufacturer Pharmaniaga for the registration and supply of ravidasvir in Malaysia and South-East Asia.[17] Registered in June 2021, ravidasvir's launch was a moving celebration of hope, a testament of what humanity can achieve when lives are put before profits.

To that end, Malaysians can be proud that the country's National Pharmaceutical Regulatory Agency (NPRA) has grown over the years to become an internationally recognised regulatory agency. Since 1996, NPRA has been a WHO Collaborative Center for Regulatory Control of Pharmaceuticals, exercising the highest standards of drug regulation through its membership of the Pharmaceutical Inspection Cooperation Scheme (PIC/S), enforcing an internationally accepted level of Good Manufacturing Practice (GMP) on industry.

In applying for the marketing approval for ravidasvir, Pharmaniaga was required to submit to NPRA the registration dossier for the drug, a complex technical package of information which included data pertaining to ravidasvir (scientific, chemistry and laboratory data, clinical and non-clinical), the detailed manufacturing process of the active ingredient and the finished product, essentially data which was required to prove the safety and efficacy of the product, as well as the intended quality. The stand was taken to engage NPRA very early on in the programme through the pre-submission meeting (PSM) platform. The PSM procedure was put in place in January 2020, whereby NPRA provides regulatory advisory service during the developmental stage of the product.

Sharifah Fauziyah Syed Mohthar, Director of Regulatory Affairs at Pharmaniaga, reflects: 'When we were approached by Pharco and DNDi to join this as a public health focused partnership with an aim to produce an NCE [new chemical entity] at the cost of a generic … we thought that's an interesting model but the word I want to use is NOBLE. It has the aim of increasing accessibility to the masses and honestly it bodes very well for Pharmaniaga's mantra of having passion for the patients. Personally as a pharmacist, knowing that we are developing a new cure is very meaningful for my profession as a whole. If we could take this model further, we are all on board to ensure that accessibility of medicines is key for all of us … This is a very proud moment for the country and is also an important step for the country's progress towards regulatory maturity.'

The entry of ravidasvir into the HCV scene has provided much-needed competition to the other DAAs. Competition is essential to driving drug prices down.[18] Dr Sherine Helmy, the CEO of Pharco, shares: 'This new treatment will be a powerful tool in our arsenal to make the vision of a hepatitis C-free world a reality … This is why this new combination will be sold at an affordable price between $300-500 for a 12-week treatment course.'

Since March 2018, the Malaysian government has rolled out free treatment in 23 public hospitals. To date, even with the COVID-19 pandemic, more than 10,000 patients have been healed of HCV with the availability of ravidasvir.[19]

The ravidasvir-sofosbuvir combination is a game changer in the fight against HCV. It will now provide the world with an affordable option, especially for the millions still waiting for access to life-saving HCV treatments in low- and middle-income countries.

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17 Ibid.

18 See the Malaysia Competition Commission (MyCC) Market Review on Pharmaceutical Sector under Competition Act 2010, 8 January 2018. Available at https://www.mycc.gov.my/market-review/final-report-market-review-on-pharmaceutical-sector-under-competition-act-2010

19 https://www.bernama.com/bm/am/news.php?id=1971837#.YMddWNYNeaY.twitter

Jean-Michel Piedagnel, South East Asia Director for DNDi, points out: 'It is important to remember what is the main model for delivering new treatment. The main model is Big Pharma … DNDi is an international not-for-profit research organisation that develops drugs for diseases where the traditional players/market are not providing drugs, usually because there is no profit to be made. We step in usually in neglected tropical diseases. We have a collaborative model, partnership, not for profit, and we focus on patients and affordability.

'A lot of us in DNDi believe: ... what's the point of medical innovation if it doesn't translate into access for patients? We are addressing this question with our model. That's why in the last 16 years we have developed eight treatments and this is the ninth one … This one is what we call an NCE. And it is like the holy grail in medical research. The NCE is an entirely new medicine. That's what ravidasvir is. It is a very good drug, very effective one…

'I never expected that when we started this journey, our collaborative model would deliver something so impressive ... The registration of [ravidasvir] in Malaysia is a stepping stone. Malaysia has totally changed its policy in terms of treatment and access, designing specific programmes to reach at-risk groups, considering treatments in prison – it's a full-blown access strategy which started with a clinical trial. Today we can say that MOH has all the tools that it needs to bring free treatment into Malaysia. And even though we might have had a catalyst role at the beginning, I think this was only achievable through real collaboration across the board. For me, it's a real pleasure to see what we have been able to achieve in Malaysia in translating innovation to access for patients in Malaysia. And now we need to go beyond Malaysia, together with Egypt, and try to make sure this treatment is made available to as many people as possible.'

Treating HCV early presents cost savings for health systems too as early treatment will reduce cases of liver cancers and cirrhosis, resulting in enormous savings to the public health system in terms of treatment costs.

Finding the missing millions

Having secured treatment, Malaysia now has to find the missing millions who are infected with HCV but remain undiagnosed. Under-screening is a major issue as many are still not aware of the disease. 'Although hepatitis can be cured, there is a vicious circle that stands in the way of providing treatment to all in need: the disease is mostly a "silent killer", the diagnostic process is complex, so people go unfound, and DAAs are often too expensive,' said Dr Noor Hisham Abdullah, Director General of Health at MOH. 'Malaysia decided to act to break this vicious circle. We are actively screening to find "missing" patients, rolling out simpler diagnostic tests, and ensuring we have access to the best prices for treatments, including by conducting clinical research to identify additional affordable treatment options. [The registration of ravidasvir] is a milestone on Malaysia's long journey to achieve the World Health Organization goal of eliminating hepatitis C by 2030.'

In line with that vision, in 2019, in collaboration with DNDi and another not-for-profit organisation, Foundation for Innovative New Diagnostics (FIND), MOH launched a one-week nationwide HCV screening campaign in conjunction with World Hepatitis Day. RDTs were introduced for the first time in 49 hospitals and 38 health clinics across the country, targeting the general adult population. The campaign was aimed at providing public awareness of the disease and insight into the effectiveness of a population-based screening programme and also at identifying HCV-infected individuals and the associated factors for HCV infection in the country. The goal is to decentralise HCV screening using RDTs, following through by linking the HCV-seropositive individuals to confirmatory testing and treatment. Ideally the plan is to provide screening services to community-based outreach agencies and private health institutions in the second phase of the campaign.[20]

On being able to tell his patients today that there is a cure for them, Dr Radzi says: 'When I reflect back, it is like a magical journey to me. No doubt we have challenges, we've had lots of problems, issues, along the way, [but] this is worth the effort. It is so fulfilling and gratifying. We are going to walk through this journey together. Until the finishing line.'

[20] https://dndi.org/wp-content/uploads/2020/06/Said-Find-Missing-Millions-Malaysias-HepatitisC-Screening-Campaign-JViralHepat-2020.pdf

South-South collaboration

On lessons learnt in the ravidasvir journey, DNDi's Piedagnel shared: 'We talk about decolonising the global health system, and I think this is typically touching on the issue that people in the Global South feel they have no value in bringing new treatments, and I totally disagree. But it takes a lot of leadership, a lot of political leadership as well as working together … we need to recognise that there is quality, there is potential to deliver treatments … Countries in the Global South need to come to terms that they have potential, especially high-middle-income countries like Malaysia, Thailand, Vietnam, those countries can make a difference. They need to work together – there is no other choice – in developing new treatments, new antibiotics, dengue treatments. I hope we see that more in the future and that what we have done with HCV will inspire people.'

This sentiment is echoed by Dr Noor Hisham: 'This is just the beginning; one opportunity leads to many other opportunities … Working together we can make the impossible possible. This will become a role model for other diseases as well, this is a very exciting integrated access strategy that will probably help us to end epidemics or diseases in this country.' He further urged top performers in Malaysian universities to take public health as one of their specialties, providing the country with her next generation of champions.

As the ones needing and receiving treatments directly, civil society also has an important role to play in the collaboration. 'We can educate ourselves and work with the government to put the right policies and laws in place, to recognise that if we do not have the industrial policies that allow us to build our own industrial capacity then we will not have that freedom to invest in public health … In 2003, when we did the first CL [compulsory licence] for HIV, the headlines said things like "breaking patents". Fast-forward to 2017, "CL gives hope". I think it is also important for the media to understand the science, the technical considerations and the law, that what we are doing is perfectly legal, is the right thing to do,' points out TWN's Chee.

What will it take, then, for Malaysia to grow in this journey? She will need to:

- forge collaborations with like-minded international organisations and other countries for joint areas of research;
- develop partnerships for setting agendas or participating more effectively in multilateral forums like WHO and the WTO;
- encourage investment from companies in the South to build expertise.

On the national front, there should be a consideration of, among other things, the national health budget, medicine expenditures and procurement policies, all relevant policies and legislation, the tax regime as well as access to finance in order to come up with a holistic plan for the development of the public health system and, within that, the growth of the local pharmaceutical industry. More specifically, the measures taken should include:

- establishing biotechnology and health funds to encourage the growth of the pharmaceutical sector and strengthen public research institutions;
- reversing the brain drain, hiring Malaysians who have gained the technical expertise overseas;
- tightening up intellectual property laws to incorporate the full measure of TRIPS flexibilities;
- implementing a government incentive scheme to encourage the growth of the pharmaceutical industry;
- establishing a long-term policy to purchase from local pharmaceutical manufacturers even if the products are a little more expensive, and implementing a pooled procurement strategy for the region.

The COVID-19 pandemic has taught us that a strong public health system and local manufacture of medicines are necessities and not options. We have now seen how insufficient investment in these areas can bring a country to its knees. The availability and accessibility of medicines is clearly more than just a medical issue.

For Dr Helmy, the man behind Pharco, his A-Z of the Egyptian story of lessons learnt is both inspirational as well as instructional for the pharmaceutical industries and public health systems of developing countries:

A: Affordability makes access

B: Believe in the cause

C: Create rules of the game

D: Direction and political will is the clue

E: Ecosystem formation

F: Funding till the snowball rolls

G: Government's support to research

H: Harmony between team members

I: Infection control

J: Join the right people together

K: Knowledge transfer

L: Logistics and economies of scale

M: Media for education and motivation

N: NGOs partnering

O: Organic growth

P: Proper planning prevents poor performance

Q: Quality, safe, affordable medicines

R: R&D is the way out

S: Strategic fit

T: Tour n' Cure is an alternative

U: United Nations (UN) umbrella

V: Values 'Love, Trust and Justice'

W: Will comes first

X: X-Pats collaboration

Y: Yield analysis and data management

Z: Zig-zag pathway, go under, go through but never stop

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