Diagnostics and Therapeutics Working Group

ACT now, ACT together to accelerate the end of the COVID-19 crisis
Council’s Therapeutics & Diagnostics Working Group

• **Objective of working group:**
  
  - Assessing current and future barriers to production, demand and accessibility to COVID-19 Therapeutics and Diagnostics, and provide recs to address barriers
  
  - streamline and support multiple member state led efforts on Dx and Tx
  
  - Highlight non-vaccine medical countermeasures

• **Co-chairs:** UK and South Africa

• **Audience:** ACT-A Facilitation Council, G7/G20 and feed into PPR discussions
# Membership of the Dx-Tx Working Group

<table>
<thead>
<tr>
<th>South Africa (co-chair)</th>
<th>United Kingdom (co-chair)</th>
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<tr>
<td>Co-chair: Mustaqeem de Gama</td>
<td>Co-chair: Ian Dalton</td>
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<tr>
<td>Canada</td>
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**Supported by:**
- Tx and Dx Pillars
- ACT-A Hub
- MPP
- EC & AU
- 2 CSO reps
- WBG
Working Group report was recently published

Report published online on 22nd Sep...

Through extensive consultation...

• Intense engagement of the Working Group between May 22 – Sept 22

• 8 Working Group meetings with 6 deep dives

• < 20 bilaterals with Working Group members, ACT-A pillars & stakeholders

• Multiple feedback sessions with the Working Group and ACT-A pillars
Overview | 16 recommended actions are provided across the value chain

Three key domains...

- Regulation and Manufacturing
- Sustainable markets & procurement
- In-country delivery & technical assistance

Time horizons...

- To be implemented as part of ACT-A transition plan between now and March 2023
- To be implemented for the long-term control of COVID-19
6 recommended actions for ACT-A Transition Plan period – March 23

**Key themes include...**

- Assessing and enhancing national diagnostic strategies
- Optimizing allocation and use of existing resources & funding
- Increasing collaboration between Industry Partners & ACT-A
- Integrating test to treat strategies into primary care and community systems

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**RECOMMENDED ACTIONS**

**2.1 Recommended actions between now and the end of March 2023:**

Sustainable markets & procurement

**Recommended action 2.1. Page 12:** Countries should assume national diagnostic strategies to be in line with WHO-Diagnostic & surveillance monitoring guidelines regarding access to self-testing. This is to achieve sufficient market demand for essential commodities and accessibility to products. Key themes include...

• Assessing and enhancing national diagnostic strategies
• Optimizing allocation and use of existing resources & funding
• Increasing collaboration between Industry Partners & ACT-A
• Integrating test to treat strategies into primary care and community systems

**See report for full & detailed set of recommended actions**
10 recommended actions relevant for long-term COVID-19 control and PPR

Key themes include...

- Supporting efforts to expedite review & regulatory processes for new products
- Enhancing generic licensing & tech transfer for therapeutics
- Increasing local development of sustainable manufacturing capacity
- Developing & funding PPR mechanisms, incl. a medical countermeasures platform
- Prioritizing market shaping for new tests & strengthening lab capacity

See report for full & detailed set of recommended actions
Dissemination channels

- Co-chairs statement to media with report referenced and attached
- Posting on ACT-Accelerator website & social media
- Reference to the report in UNGA Foreign Ministerial, High Level UNGA event & possibly G20
Report is just ‘the start’ and a contribution to ongoing Tx & Dx work

Need your support to:
- Follow up on the recommended actions relevant for member states
- Share the report with the Ministries of Health
- Advocate the findings of the report in key fora e.g PPR discussions
External Evaluation of the Access To COVID-19 Tools Accelerator (ACT-A)

6 October 2022
Table of contents

1. Objectives of the external evaluation
2. Methods and data
3. Key findings
   - Operating model
   - Financing
   - Performance
   - External factors
4. Lessons learnt and recommendations
Objectives of the external evaluation of ACT-A

- The external evaluation was a forward-looking exercise, which was carried out between July 11 and October 10, 2022.
- Its main objective was to learn from ACT-A and to identify key lessons learnt for future pandemic preparedness and response.
- Focus on six areas:
  1. Mandate
  2. Set-up and structure
  3. Resource mobilization/financing
  4. Achievements
  5. Gaps and missed opportunities

- The evaluation was not an impact evaluation.
- It did also not aim to provide a detailed description of all ACT-A activities.
- Instead, the aim was to assess the 24 evaluation questions from the Terms of Reference (ToR).
Methods and data
The evaluation is based on a mixed-method design. Four complementary methods were used to collect data:

(i) A document and database analysis
(ii) Semi-structured key informant interviews and focus group discussions
(iii) Online surveys
(iv) Online platform for open-ended stakeholder submissions.

The data was collected between August 1 and September 20, 2022.
101 key informant interviews with a diverse set of stakeholders

**Total key informant interviews**

- Academia/Experts
- Act-A Envoy
- Co-convening agencies
- CSO
- Facilitation Council (HIC)
- Facilitation Council (MIC)
- Low- and middle-income country
- Other
- Private sector
- Regional organization

*Includes 10 focus group participants*
Online surveys

- Detailed survey
  FC and co-convening agencies (n=27)
  - 56% (FC/others)
  - 44% (Co-convening agencies)

- CSOs and academia/experts (n=24)
  - 29% (Academia/experts)
  - 71% (CSOs)

- Low- and middle-income country governments (n=20)
  - 5% (Asia)
  - 15% (East Africa)
  - 30% (Latin America)
  - 15% (Southern Africa)
  - 35% (West Africa)
Databases

- The **Global COVID-19 Access Tracker** ([https://www.covid19globaltracker.org/](https://www.covid19globaltracker.org/)) to track progress towards the global targets for access to COVID-19 vaccines, treatment including oxygen, tests, and personal protective equipment (PPE). The access tracker draws on multiple databases, including the following from which we extracted data:

  - The **ACT-Accelerator Commitment Tracker** ([https://www.who.int/publications/m/item/access-to-covid-19-tools-tracker](https://www.who.int/publications/m/item/access-to-covid-19-tools-tracker)) to track funding commitments made by donors against ACT-Accelerator Pillar budgets (including fair-share calculations).

  - The **UNICEF COVID-19 Market Dashboard** ([https://www.unicef.org/supply/covid-19-market-dashboard](https://www.unicef.org/supply/covid-19-market-dashboard)) to track overall vaccine deliveries, COVAX deliveries, overall vaccine donations, and COVAX donations overtime across countries as well as syringe and safety box deliveries across countries.

  - **WHO Coronavirus Dashboard**, which includes data on COVID-19 cases, deaths, and vaccinations ([https://covid19.who.int/](https://covid19.who.int/)).

- Triangulation of all data (KII; survey; platform submissions, document and database review)
Key findings:
ACT-A’s operating model
ACT-A’s operating model was the best possible structure at the time of its launch

- When ACT-A was set-up, a rapid response to the COVID-19 pandemic was considered as the main priority.
- Establishing new structures was widely considered unrealistic given the urgent need for a speedy response.
- Most key informants commended the creation of ACT-A in a highly challenging environment, appreciating the counterfactual – an uncoordinated global response
- This is also reflected in the results of the online survey: Two-thirds of survey respondents (66.0%) agreed that ACT-A’s operating model was the best possible structure at the time of the launch.
A different model is needed for future pandemic response

- ACT-A’s informal coordination model is insufficient for a future pandemic response. A different design will be needed to address future pandemics.

- Almost two-thirds (65%) of respondents think we need a different model for future pandemic response.

- Major areas of concern were raised:
  - Limited cross-pillar/within-pillar coordination
  - Insufficient accountability
  - Too little involvement of low- & middle-income countries
  - Role of Health Systems & Response Connector (HSRC)
Cross-pillar coordination was perceived as too limited

- Principal Group meetings were considered useful – light-touch coordination. ACT-A Hub and Special Envoys contributed
- Coordination among leads did not always trickle down to lower management levels
- Overall cross-pillar coordination was perceived as too limited. 58% of co-convening agencies “somewhat disagreed” that cross-pillar coordination was effective
- Limited upstream collaboration – need for sustained/enhanced R&D collaboration
- Downstream – limited coordination on delivery; HSCR disconnected

ACT-A’s operating model enabled an effective coordination of the COVID-19 response across its four pillars.

Overall (N=17)
- Strongly agree: 7.4%
- Somewhat agree: 40.7%
- Neither agree nor disagree: 3.7%
- Somewhat disagree: 40.7%
- Strongly disagree: 7.4%

Co-convening agency (N=12)
- Strongly agree: 41.7%
- Somewhat agree: 58.3%

Facilitation council/other (N=15)
- Strongly agree: 13.3%
- Somewhat agree: 40.0%
- Neither agree nor disagree: 6.7%
- Somewhat disagree: 26.7%
- Strongly disagree: 13.3%
The coordination within the different pillars varied considerably

- Coordination within the pillars worked best for the Vaccines pillar due to longstanding working relationships.
- Other vertical pillars were more fragmented due to less well-established working relationships and lack of clear leads.
- Least effective coordination in HSCR – multiple reasons: insufficient planning; broad systems focus; no strong leadership/discordant views; “residual” role.
- The decentralized and multi-layered decision-making model slowed down the response. Only half of the co-convening agencies agreed that ACT-A’s operating model enabled effective within-pillar collaboration.

![Chart](chart.png)
Speedy response prioritized over broad inclusion

- LICs and LMICs insufficiently included, resulting in a lack of ownership and affecting delivery:
  - Key informants reported strong focus on development and procurement of MCMs, with insufficient focus on delivery aspects and country readiness
  - Delivery aspects would likely have received more attention if LICs and LMICs were meaningfully included
  - For example, strong need for oxygen but initially insufficient attention to supply (situation improved substantially with Tx pillar)
- Early inclusion of LICs and LMICs was also considered critical to create ownership for mandates and objectives and to ensure that a delivery lens is fully integrated from the beginning
- Inclusion of CSOs improved over time – represented in pillar workstreams, Council etc.
Accountability and transparency were not sufficiently promoted

- ACT-A had multiple decision-making centres and uneven arrangements for information sharing, resulting in limited accountability for funding and results.

- Survey data underscored this: Only 38% of respondents agreed that ACT-A promoted sufficient accountability; 48% disagree.

- Countries also reported lack of transparency and predictability for MCM delivery.
Key findings: Financing
ACT-A raised substantial funding, yet it faced significant funding gaps

- ACT-A mobilized US$23.5 billion
  - US$17.8 billion pledged before October 29, 2021
  - US$5.7 billion pledged after October 29, 2021
- Substantial but insufficient
- Significant funding gaps across both periods
  - Gap for 2020-2021: US$15.4 billion
  - Gap for 2021-2022: US$11.1 billion
- Vaccines Pillar mobilized over two-thirds of total funding

Source: ACT-A Commitment Tracker
Joint resource mobilization was a successful approach to fundraising

- Joint resource mobilization was perceived to add value (74% of survey respondents)
- The fair-share model was also perceived as useful, but in future, the model would have to be agreed upon in advance to ensure broad ownership
- Views mixed on need for complementary funding pool with ability to allocate resources based on need

ACT-A’s joint resource mobilization model added value to the global COVID-19 response compared to uncoordinated fundraising by individual agencies.
Funding was not mobilized at sufficient speed

- Key informants highlighted that the lack of early funding was a barrier to a swift response.
- Initial donor pledges to ACT-A were made in mid-2020, but agencies only received funding months later.
- Particularly, the co-convening agencies expressed their dissatisfaction in the survey: Only 18% considered the speed of resource mobilization sufficient.
- Need for day zero funding in future.
Key findings: Performance of ACT-A and its pillars
54% of surveyed stakeholders were satisfied with ACT-A - 22% were dissatisfied
The Vaccines Pillar

- **Upstream:**
  - Contributions to the development of COVID-19 vaccines (esp. Novavax but also Oxford/AZ; less Moderna)
  - Indemnification/liability scheme incl. no-fault compensation mechanism
  - Smaller contributions to tech transfer and manufacturing

- **Downstream:**
  - COVID-19 vaccine rollout has been the fastest in global history and unprecedented in scale (see also survey – 7.5)
  - As of September 15, 2022, COVAX delivered 1.72bn
  - By end of 2021, 832m doses to AMC, almost achieving the AMC target (950m); 953m doses overall, with 46% donations
  - Self-financing arm: Perceived as of limited use; consulted UMICs dissatisfied
  - Global procurement model too ambitious; a more targeted approach is suggested for future response
  - Humanitarian buffer did not work for non-governmental humanitarian agencies (indemnification)
Diagnostics Pillar

- **Upstream:**
  - Negotiated low prices for rapid & molecular tests
  - Support to genomic sequencing
  - R&D and product assessments (e.g., review of tests; clinical evaluations test performance to facilitate regulatory approvals)
  - Support manufacturing (e.g., licensing agreements to expand the manufacturing of COVID-19 tests to LICs and LMICs)
  - Evidence for demand forecasts and needs assessments

- **Downstream:**
  - Original target: 500m simple, accurate, affordable tests by mid-2021 - 146m million procured/97m delivered by end of 2021
  - Low-test rate in LICs (0.04/1000, at end of Q2, 2022)
  - Some factors: Initial upstream focus; late WHO clearance, esp. for self-tests; demand

On a scale of 1-10, with 10 being the best, how would you rate the performance of the diagnostics pillar to improve access to COVID-19 diagnostics in the Dx144 countries?
The Therapeutics Pillar

- **Upstream:**
  - Complex science (R&D on drugs for acute viral infections difficult)
  - Also held back by multiple/insufficiently coordinated efforts ("loose alliance"), and limited funding (compared to Vx)
  - Supported research that identified dexamethasone as the first life-saving therapy for COVID and provided guidance on its use
  - Reached licensing agreements for the generic production and distribution of nirmatrelvir (Paxlovid) and generic manufacturing of molnupiravir (with Med. Patent Pool)

- **Downstream:**
  - Pillar did not achieve its original delivery targets (245 million treatment courses by mid-2021)
  - Oxygen delivery substantially improved since the pillar took responsibility and Oxygen Emergency Taskforce was created (Feb. 2021)
  - Test & Treat strategy should have been prioritized earlier – since June 2022, Working Group exists

On a scale of 1-10, with 10 being the best, how would you rate the performance of the therapeutics pillar to improve access to COVID-19 drugs in low-income countries, lower-middle-income countries, and key upper-middle-income countries?
Most key informants described the pillar as ineffective over large parts of 2020 and 2021:

- Misconceived: Not feasible to strengthen health systems during pandemic
- It should have been a mechanism to hardwire MCMs into country systems
- Underfunded
- Leadership changes
- Not the same level as vertical pillars: strategic planning, clarity on focus, strategic direction, and roles and responsibilities
- “Residual” taking over all the activities that other pillars did not want to pursue

The median ranking across survey respondents was 3.5, the lowest rating given for any of the functions performed by any of the pillars

Pillar made contributions to PPE
CoVDP successful in supporting countries with the lowest vaccination coverage: 16 of the 34 countries have now coverage rate of at least 20%.

Key findings: External factors
## Top 3 external factors affecting the performance of ACT-A and its four pillars

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<th>Co-convening agencies</th>
<th>FC</th>
<th>CSOs and academia</th>
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<tr>
<td>Manufacturing capacities</td>
<td>Commitments for global access</td>
<td>Manufacturing capacities</td>
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<tr>
<td>Member state responses to COVID-19</td>
<td>Manufacturing capacities</td>
<td>Export bans</td>
<td>Member state responses to COVID-19</td>
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<tr>
<td>“Last mile” implementation</td>
<td>Export bans</td>
<td>“Last mile” implementation</td>
<td>Technology transfer</td>
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Lessons learnt and recommendations
Lessons learnt and recommendations are structured around four areas

<table>
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<th>R&amp;D coordination</th>
<th>MCM funding platform (AFC)</th>
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<td>Global functions</td>
<td>Strengthening regional manufacturing and country systems</td>
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**Key findings**

- **Increased R&D coordination and leadership** are essential to develop MCMs for future pandemics.
  - The evaluation found that the agencies working on R&D did not sufficiently coordinate their R&D efforts across and to some extent also within the pillars.
  - **Clear leadership is critical to mobilize attention to and investments in R&D**, and to facilitate and oversee progress across the pipeline to the delivery and uptake of new tools.
- **Structures with clear lead agencies for R&D on diagnostics, therapeutics, and vaccines** are instrumental – based on the three vertical pillars
- **A joint platform could coordinate the work across the three product areas.**

**Recommendations**

- **Enhance coordination through three permanent MCM platforms** for each product type, with defined leads for diagnostics, therapeutics, and vaccines.
- **R&D agencies should create a joint platform to facilitate coordination**, including on:
  i. scientific exchange
  ii. priority setting for the R&D agenda and investments
  iii. technology transfer and IP management to create competitive markets and the availability of low-cost products.
Contingent funding platform for MCMs

**Key findings**

- The evaluation showed that **contingent funding for at-risk procurement of MCMs must be available on day zero** of the next pandemic.
- Even with early and contingent funding in place, additional funding will be necessary, which will require a coordinated resource mobilization approach.
- **Transparent decision-making and broad and early inclusion of countries and civil society** is a requirement for success.
- Funding should target countries with the lowest income.
- **Strengthening health systems during an emergency is not possible**. This needs to happen in-between pandemics. Instead, an interagency mechanism to hardwire MCMs into country systems will be important.
- **A future system should be prepared for donations**, which may play a role again.

**Recommendations**

- **Establishing an Advanced Commitment Facility with a credit line to ensure availability of funding on day zero.** Key features:
  - **Day zero funding**: Pooled fund for initial allocation for R&D/at-risk procurement, which requires decision-making body to allocate funds across product types.
  - **Resource mobilization**: Build on ACT-A’s coordinated model to mobilize direct pledges to individual agencies; potentially complement by a pooled fund to allocate funding flexibly according to scientific evidence and need.
  - **Governance**: Strong representation of regional actors and opportunities for regional procurement (“club of buyers”); participation of low- and middle-income countries and CSOs; better coordination between pillars; stronger accountability.
  - **Scope and delivery**: Targeted funding for countries with lowest income; Set-up interagency model for delivery, with narrow focus to countries in greatest need of support and led by an operational agency (‘CoVDP-model’). Needs to include all MCMs; rapid creation of mechanisms for management of donations.
Global functions

Key findings

- There is a **need for global leadership** to keep pandemic preparedness and response high on the global agenda, to track progress, and to provide high-level political guidance and oversight.

- **Indemnification and no-fault compensation** mechanisms were a key contribution of COVAX. The lack of a workable mechanism for non-governmental actors was a challenge for the Humanitarian Buffer.

- **Technology transfer** is crucial and stronger emphasis is needed in the future.

- **Fast prequalification** of diagnostics is needed to enable rapid availability during emergencies.

- Multiple databases and tracking platforms and approaches were created, with an increasing need to develop joint frameworks for data collection to ensure better tracking and reporting across countries and agencies.

Recommendations

- **Sustain global leadership by creating a body** (e.g., under UNGA; G20) with a small secretariat. **Ensure inclusion of LMIC governments** beyond G20.

- Develop an indemnification scheme that also works for non-governmental humanitarian actors.

- Leverage discussions on a pandemic treaty to facilitate the development of more equitable access agreements.

- Strengthen WHO’s prequalification capacity for diagnostics.

- Align on a joint framework for data collection to ensure better tracking and reporting across countries and agencies.
## Key findings

- **Building regional manufacturing capacity in a sustainable manner is critical.**
  - The lack of (vaccine) manufacturing capacity was identified as the key external barrier of ACT-A. Multiple efforts are underway to strengthen to build more manufacturing capacity across regions, for example through WHO’s mRNA hubs in Africa. These need to be supported.

- **Health systems of countries must be strengthened in-between pandemics.**
  - Strengthening country health systems, and especially primary health care systems, during “peace time” is imperative (e.g., surveillance, workforce, supply chains).
  - Donor and low- and middle-income countries themselves have to jointly ensure that the systems are ready when the next pandemic hits.

## Recommendations

- **Support efforts to establish (vaccine) manufacturing capacity across regions**

- **Fully resource the FIF and other relevant mechanisms to improve pandemic preparedness systems**
Update on our ACT-A Transition plan

Facilitation Council Technical Briefing

06 OCTOBER 2022

ACT now, ACT together to accelerate the end of the COVID-19 crisis
**Overall objective:** this next phase of work is primarily about supporting the transition to long-term COVID-19 disease control

- From emergency response to endemic disease
- Maintaining readiness for COVID-19 surges

**Transition ACT-A’s work to long-term COVID-19 disease control**

**Transition relevant aspects of ACT-A to a future PPR countermeasures platform**

- What ACT-A lessons can we build on?
- How to transition aspects of ACT-A?

...should be addressed as part of ongoing discussions on the future global health architecture

Based on feedback of ACT-A Pillar Co-Convenors & others.
Key areas of focus for next 6-months: enabling sustained access to tools for the long-term, while maintaining readiness to surge

ACT-A will support the transition to long-term COVID-19 control by:

i. **Focusing R&D & market shaping activities** to ensure a pipeline for new and enhanced COVID-19 tools

ii. **Securing institutional arrangements** for sustained access to COVID-19 vaccines, tests and treatments

iii. **Concentrating delivery** work on new product introduction and protection of priority populations, in support of national and international targets

Maintaining readiness to provide surge support as needed
Planning in the face of uncertainty: our base case reflects the current epidemiology and response, but with the capacity to surge as needed

Current situation

Ongoing outbreaks
Continued evolution of SARS-CoV-2 but existing tools remain effective

Health and economic impacts are manageable

Relatively stable demand for tools

Possible scenarios requiring ACT-A surge support

1
Global surge in disease
More transmissible variants with tools partially effective

Significant impact on health systems with impact on global economy

Demand for existing tools

2
Global surge in disease & mortality
New highly transmissible variants with at least some tools not working

Major impact on health with significant impact on global economy

Demand for scarce tools
Contents: overview of ACT-A activities in the Transition plan

Overview of how each Pillar will transition

- Narratives on changes in pillar operating context & implications for near-term priorities
- Summary of Pillar ‘start, stop, stand-by’ plans including what will be taken forward by agencies as part of their core activities

Support functions during transition

- Details on consolidation of coordination & support functions while ensuring readiness to reactivate if needed
Contents: overview of ACT-A financing in the Transition plan

Exercise 1: Validate pillar & agency financing for the next 6 months

Ongoing outbreaks
Continued evolution of SARS-CoV-2 but existing tools remain effective

Health and economic impacts are manageable

$?

Exercise 2: Estimate resources that would be needed to respond to each of the surge scenarios

Possible scenarios requiring ACT-A surge support

1. Global surge in disease
More transmissible variants with tools partially effective
Significant impact on health systems with impact on global economy
↑ demand for existing tools

$$ - $$$?

2. Global surge in disease & mortality
New highly transmissible variants with at least some tools not working
Major impact on health with significant impact on global economy
↑↑ demand for scarce tools

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**Content:** updated information on budgets by pillar

**Illustrative view of budget by pillar for the next 6 months (for the base case)**

In US$ billion

Sample questions/variables we are addressing as part of the validation process:

- R&D costs for enhanced and/or variant-adapted vaccines; delivery costs
- Introduction of new antivirals & Test & Treat strategies; impact of energy prices on oxygen

![Illustrative view of budget by pillar for the next 6 months](image-url)
Next steps: production timeline & upcoming milestones for the Transition Plan

- **Week of Oct 17**
  - Pillars complete final review of Transition Plan

- **Fri Oct 21**
  - Final draft Transition Plan shared with Council

- **Fri Oct 28**
  - 12th Council and public release of Plan & annexes

- **Week of 10 Oct**
  - Pillars to share validated costs & high-level surge estimates

- **Wed 19 Oct**
  - FinRM WG Update on costing exercise (tbc)

- **Weds 26 Oct**
  - Final comments due on Transition Plan