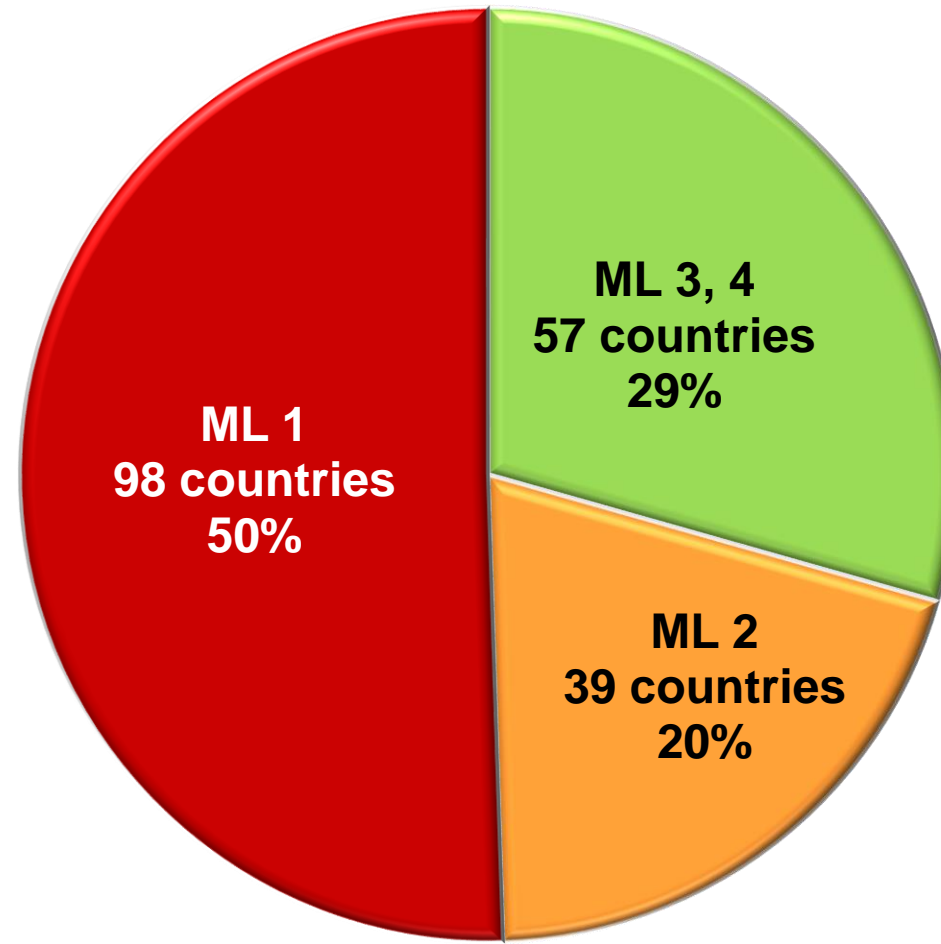

Status of regulatory and ethics procedures

for WHA 75 8 report

*Analysis of 8 sub-indicators across 34 countries formally benchmarked
Generated by RSS GBT administrator system on 08-12-2022*

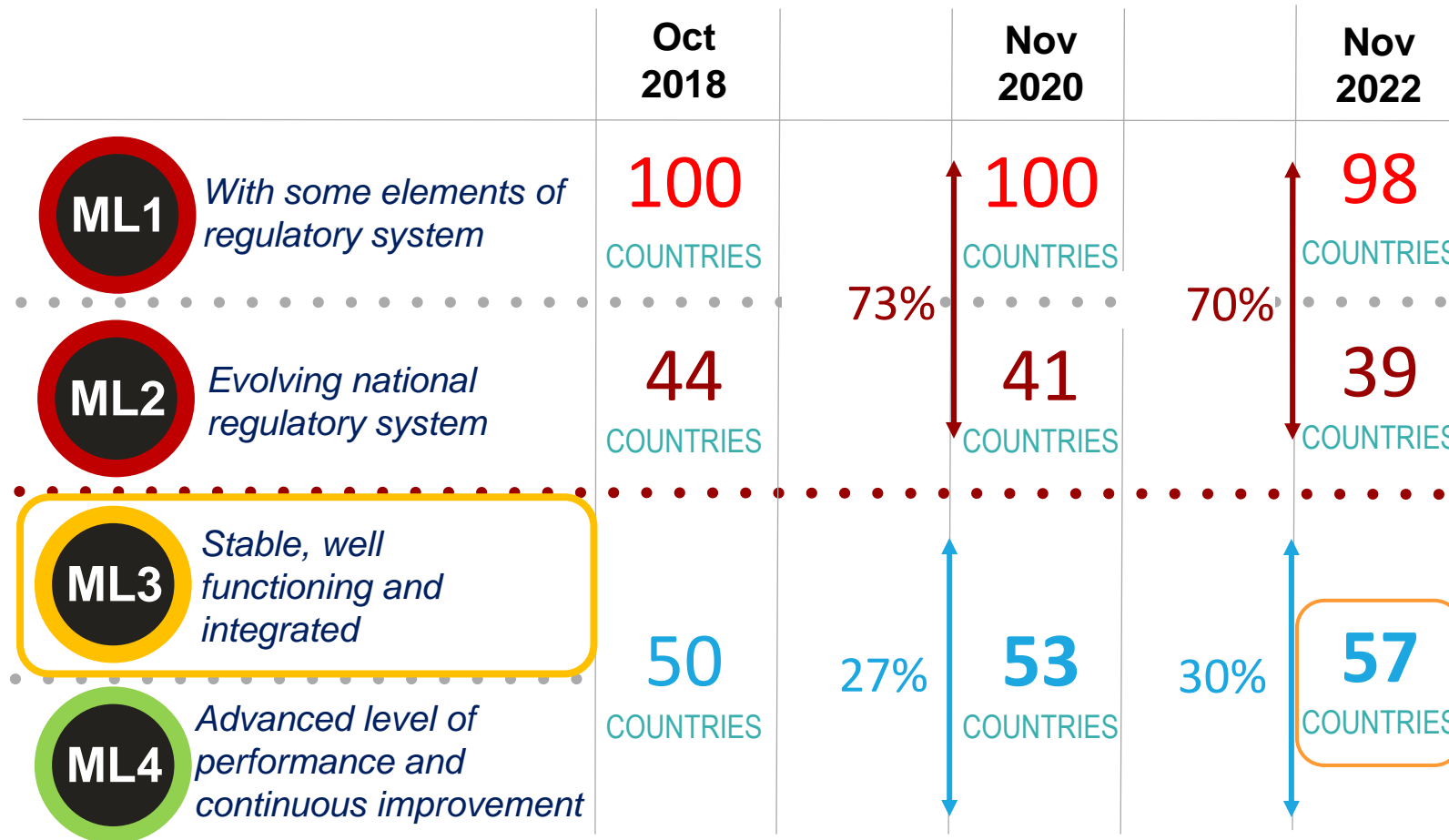
Overall regulatory systems' maturity level of WHO Member States



Dec 2022

Current levels of maturity of national regulatory systems

WHO GBT (for medicines and vaccines: as of Nov 2022)



Vaccines developed in countries with weak regulatory systems, i.e., ML1/ML2, are not eligible for EUL or prequalification

ML3 **GOAL of WHA Resolution 67.20**

ML: (regulatory system) maturity level

- [Singapore](#) medicines regulatory system, the world's first to achieve maturity level (ML4) (Feb 2022)
- [Egypt](#) and [Nigeria](#) medicines regulatory systems reach ML3 (Mar 2022)
- [China's](#) vaccine regulatory system reaches ML3 (Jul 2022)
- [South Africa's](#) vaccine regulatory system reaches ML3 (Oct 2022)
- [Republic of Korea](#) achieves the highest WHO level for regulation of medicines and vaccines (Nov 2022)

WHO Regulatory System Strengthening Programme

Global status of benchmarking of regulatory systems (2016 – Dec 2022)

Self Benchmarking

- | | |
|--------------------------------------|--------------------------|
| 1. Algeria | 30. Lebanon |
| 2. Afghanistan | 31. Liberia |
| 3. Albania | 32. Madagascar |
| 4. Angola | 33. Malawi |
| 5. Benin | 34. Malaysia |
| 6. Bhutan | 35. Maldives |
| 7. Bosnia and Herzegovina | 36. Mali |
| 8. Botswana | 37. Mauritania |
| 9. Burkina Faso | 38. Mauritius |
| 10. Cameroon | 39. Mongolia |
| 11. Cape Verde | 40. Montenegro |
| 12. Central African Republic | 41. Namibia |
| 13. Chad | 42. Nepal |
| 14. Comoros | 43. Niger |
| 15. Democratic Republic of the Congo | 44. North Macedonia |
| 16. Costa Rica | 45. Pakistan |
| 17. Cote d'Ivoire | 46. Panama |
| 18. Djibouti | 47. Peru |
| 19. Equatorial Guinea | 48. Philippines |
| 20. Eswatini | 49. Republic of Congo |
| 21. Gabon | 50. Senegal |
| 22. Gambia | 51. Seychelles |
| 23. Guinea | 52. Sierra Leone |
| 24. Guinea-Bissau | 53. Syrian Arab Republic |
| 25. Honduras | 54. Togo |
| 26. Iraq | 55. Tunisia |
| 27. Islamic Republic of Iran | 56. Ukraine |
| 28. Jordan | 57. Zambia |
| 29. Kyrgyzstan | |

Benchmarking

1. Bangladesh
2. Burundi
3. Cambodia
4. People's Republic of China
5. El Salvador
6. Egypt
7. Eritrea
8. Ethiopia
9. Ghana
10. India
11. Indonesia
12. Kazakhstan
13. Kenya
14. Lao People's Dem Rep
15. Mozambique
16. Nigeria
17. Papua new guinea
18. Rwanda
19. Saudi Arabia
20. Serbia
21. Singapore
22. Somalia
23. South Africa
24. South Korea
25. South Sudan
26. Sri Lanka
27. Sudan
28. Türkiye
29. United Republic of Tanzania
30. Thailand
31. Timor-Leste
32. Uganda
33. Viet Nam
34. Zimbabwe



World Health Organization

91

=

73%

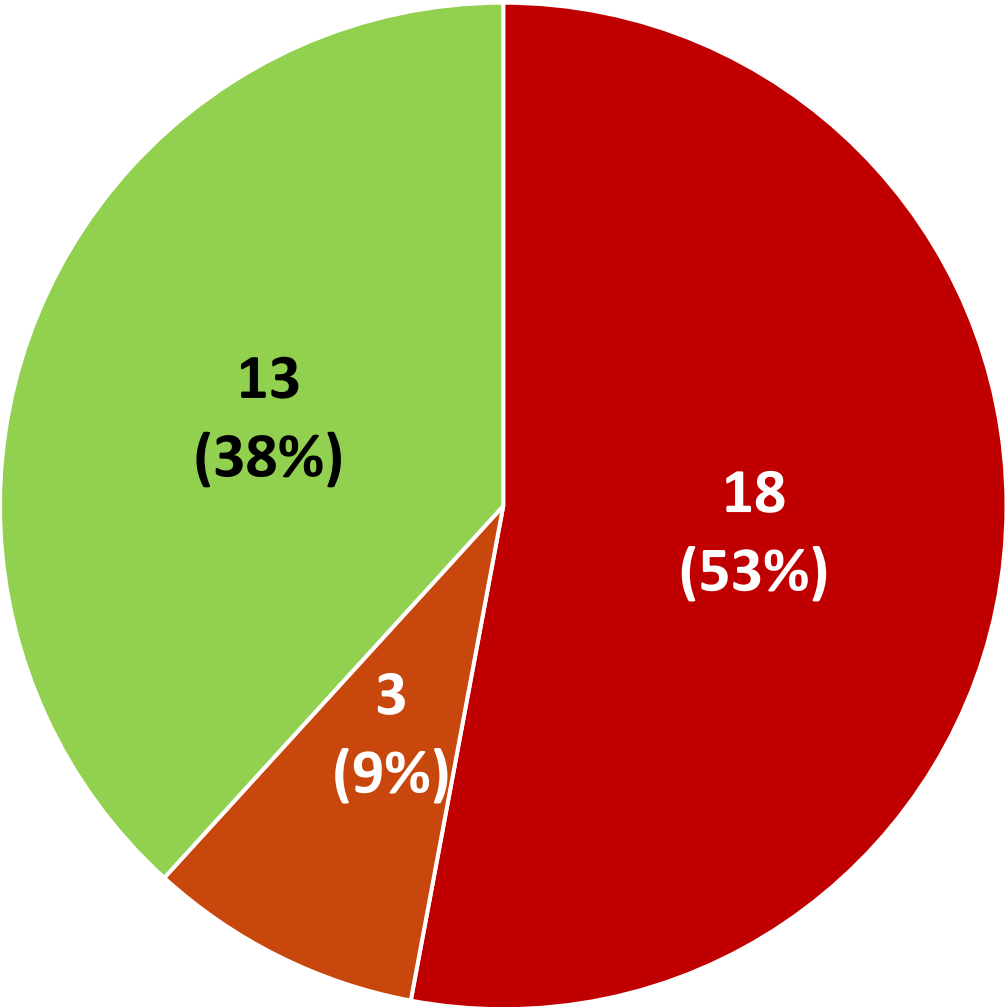
Member-states

World population

Overall status of formally benchmarked countries

34 countries benchmarked by WHO between 2016 to December 2022

- ML 1
- ML 2
- ML 3, 4



Analysis of some of the Clinical Trial indicators for the 34 countries benchmarked by WHO between 2016 to December 2022

CT01.01: Legal provisions and regulations for clinical trials (CTs) oversight exist.

CT01.05: There are legal provisions or regulations covering circumstances in which the routine CT evaluation procedures may not be followed (e.g. for public-health interests)

CT01.07: There are legal provisions or regulations that require the establishment of an IEC

CT01.11: Legal provisions or regulations allow the NRA to recognize and use relevant CT decisions, reports or information from other NRAs or from regional and international bodies

CT02.01: There is a defined structure with clear responsibilities to conduct CT oversight activities

CT04.02: The existence of the ECs with clearly defined composition

CT04.04: There are defined roles for ECs at all levels (e.g., national, sub-national, or institutional)

CT05.01: There is clarity about the funding of the EC and its members

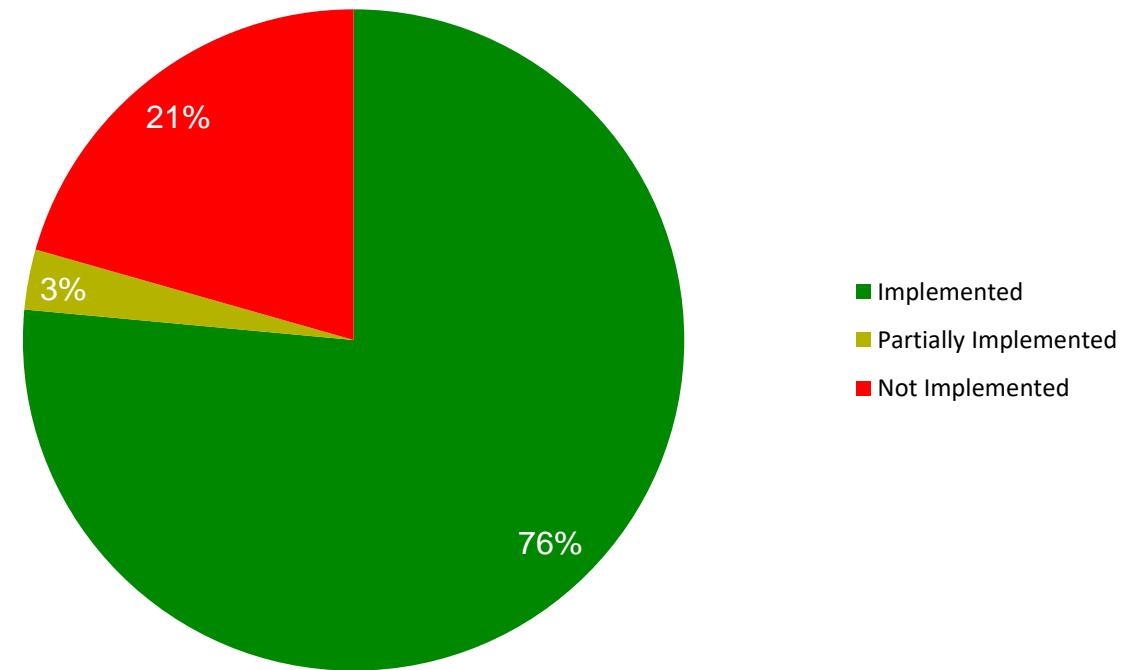
Subindicators list and their respective maturity levels

| Sub-indicator | ML |
|---|----|
| CT01.01: Legal provisions and regulations for clinical trials (CTs) oversight exist. | 1 |
| CT01.05: There are legal provisions or regulations covering circumstances in which the routine CT evaluation and procedure may not be followed (e.g. for public-health interests) | 2 |
| CT01.07: There are legal provisions and /or regulations that require the establishment of an independent ethics committee (IEC) | 2 |
| CT01.11: Legal provisions and/or regulations allow the NRA to recognize and use relevant clinical trial decisions, reports or information from other NRAs, or from regional and international bodies. | 1 |
| CT02.01: There is a defined structure with clear responsibilities to conduct clinical trial oversight activities | 2 |
| CT04.02: The existence of the ethics committees (ECs) with clearly defined composition. | 3 |
| CT04.04: There are defined roles for ECs at all levels (e.g. national, subnational, or institutional). | 3 |
| CT05.01: There is clarity about the funding of the ethics committee and its members | 3 |

CT01.01: Legal provisions for clinical trials

ML: **1**

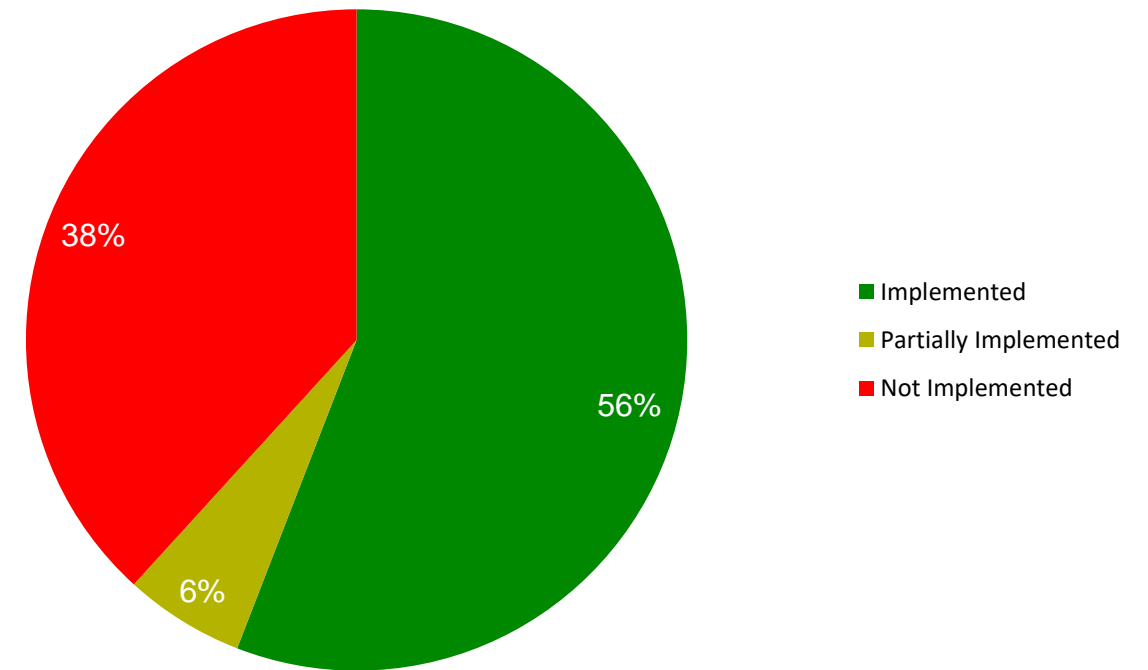
| Status | # |
|-----------------------|----|
| Implemented | 26 |
| Partially Implemented | 1 |
| Not Implemented | 7 |



CT01.05: Emergency clinical trial evaluations

ML: **2**

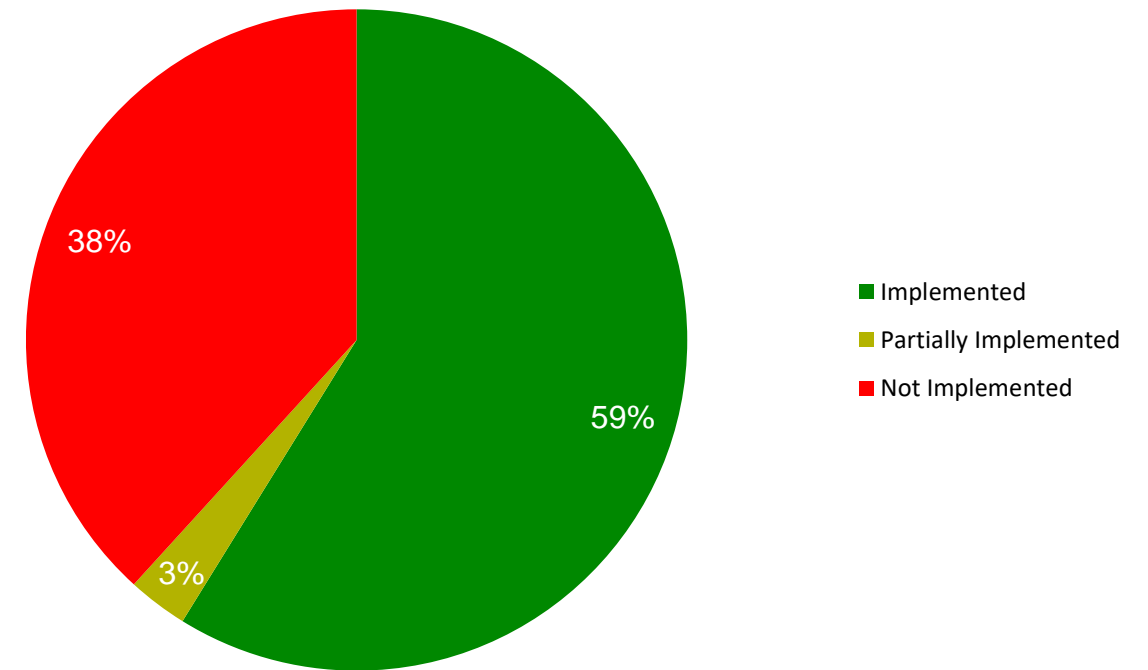
| Status | # |
|-----------------------|----|
| Implemented | 19 |
| Partially Implemented | 2 |
| Not Implemented | 13 |



CT01.07: Independent ethics committee (IEC)

ML: **2**

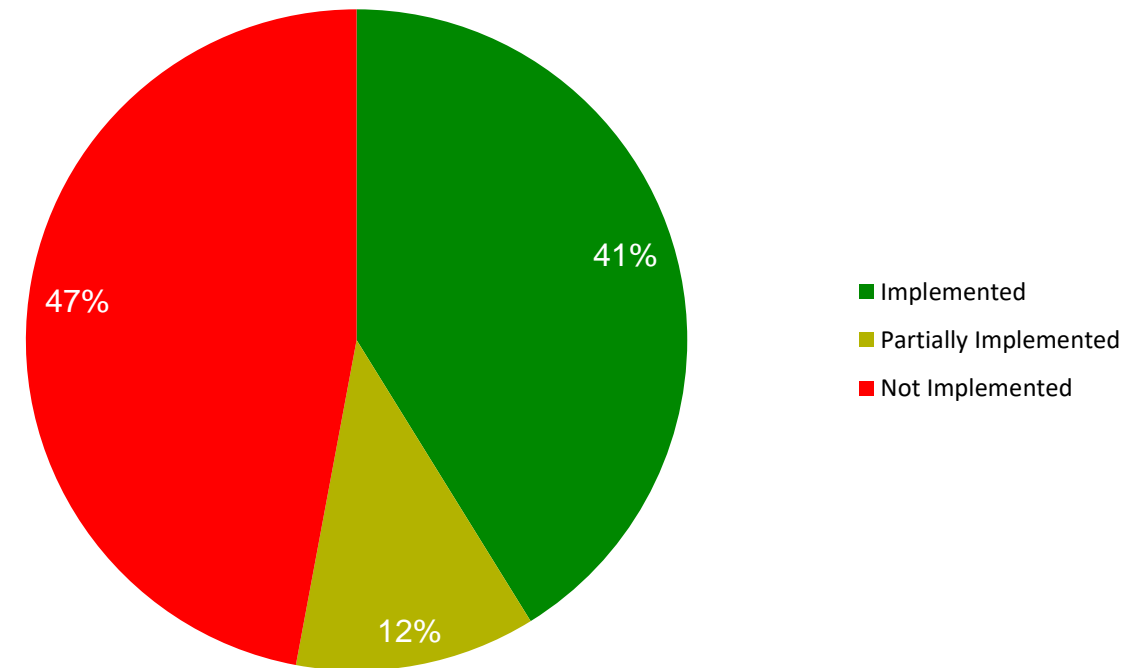
| Status | # |
|-----------------------|----|
| Implemented | 20 |
| Partially Implemented | 1 |
| Not Implemented | 13 |



CT01.11: Use of reliance for clinical trial oversight

ML: **1**

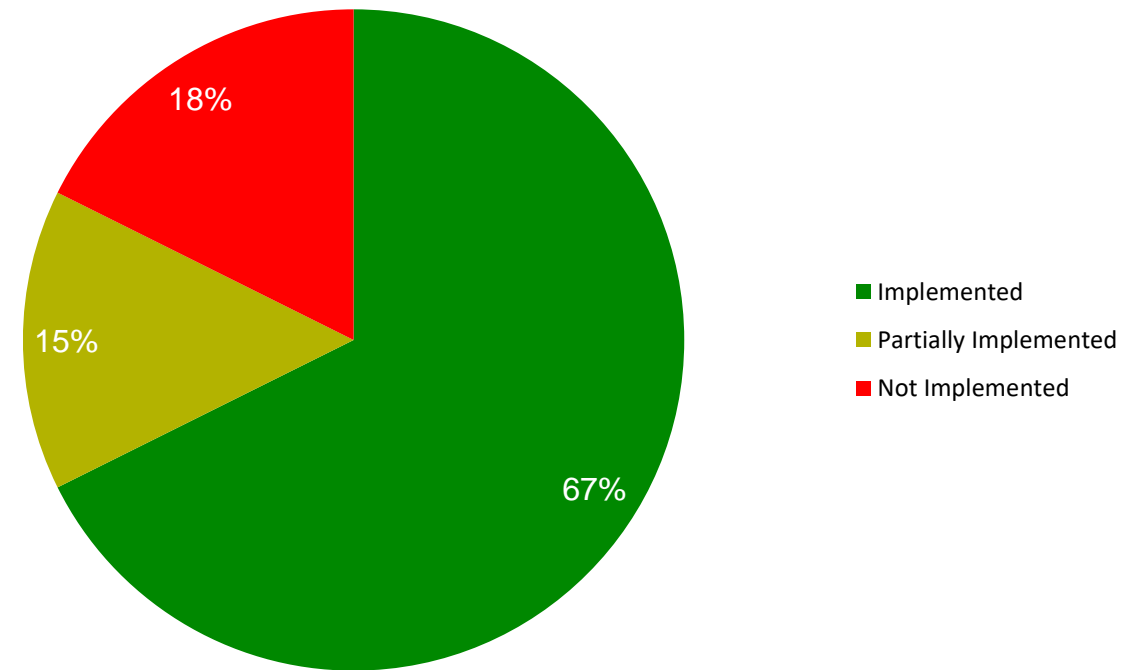
| Status | # |
|-----------------------|----|
| Implemented | 14 |
| Partially Implemented | 4 |
| Not Implemented | 16 |



CT02.01: Defined structures with clear responsibilities for clinical trial oversight activities

ML: **2**

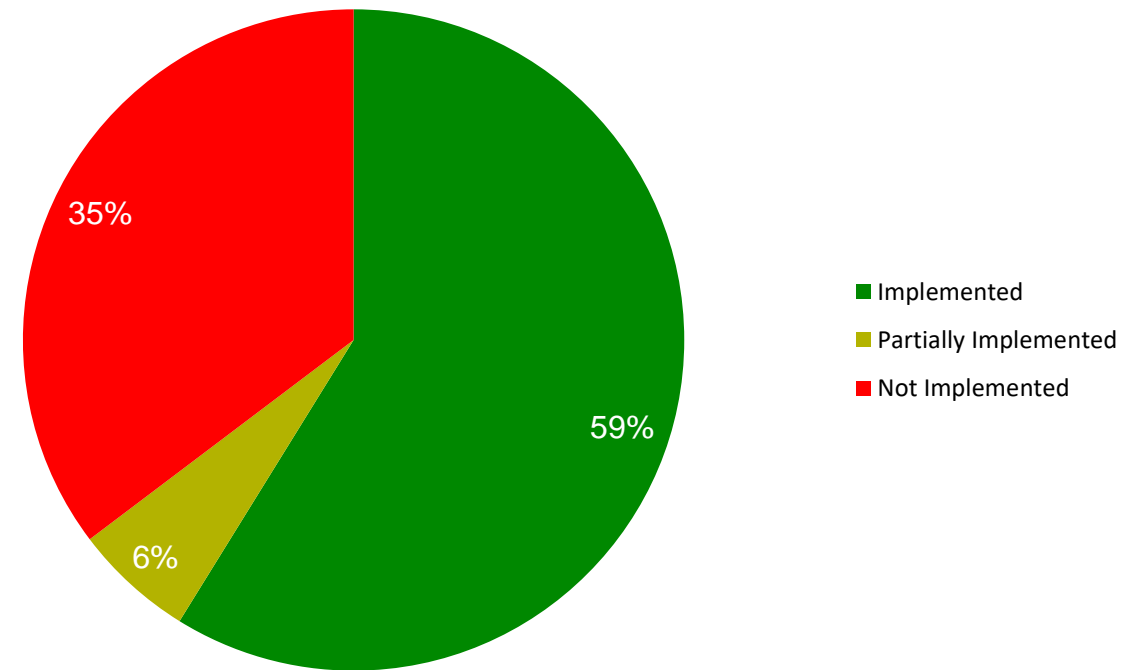
| Status | # |
|-----------------------|----|
| Implemented | 23 |
| Partially Implemented | 5 |
| Not Implemented | 6 |



CT04.02: Defined composition for the ECs

ML: **3**

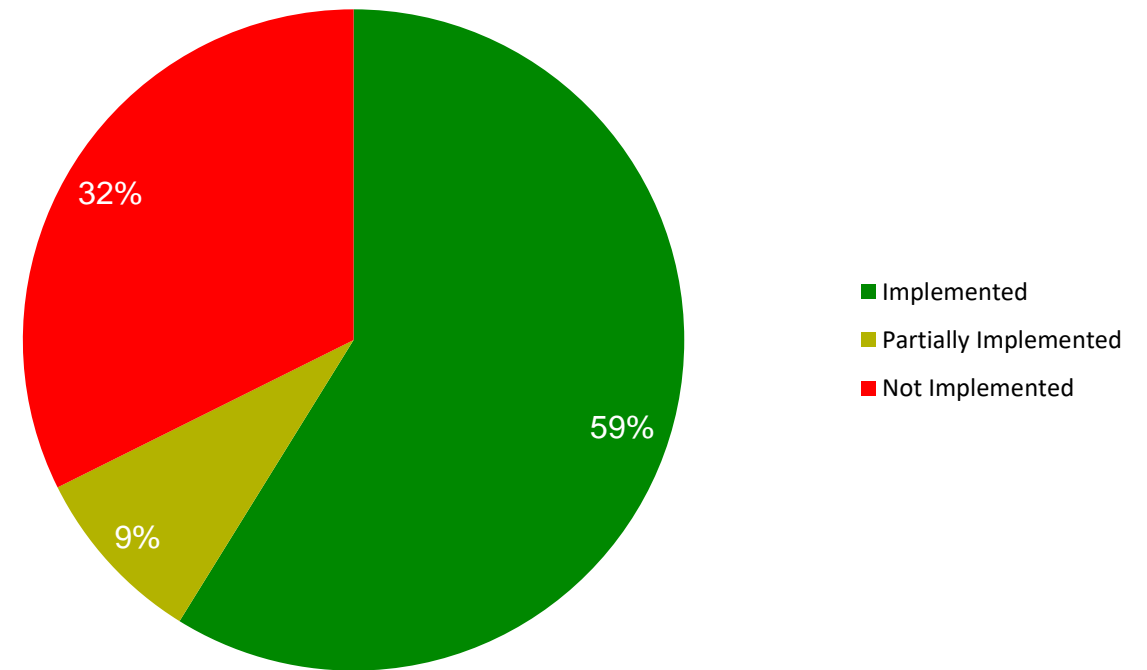
| Status | # |
|-----------------------|----|
| Implemented | 20 |
| Partially Implemented | 2 |
| Not Implemented | 12 |



CT04.04: Roles for ECs at all levels (e.g. national, subnational, or institutional).

ML: 

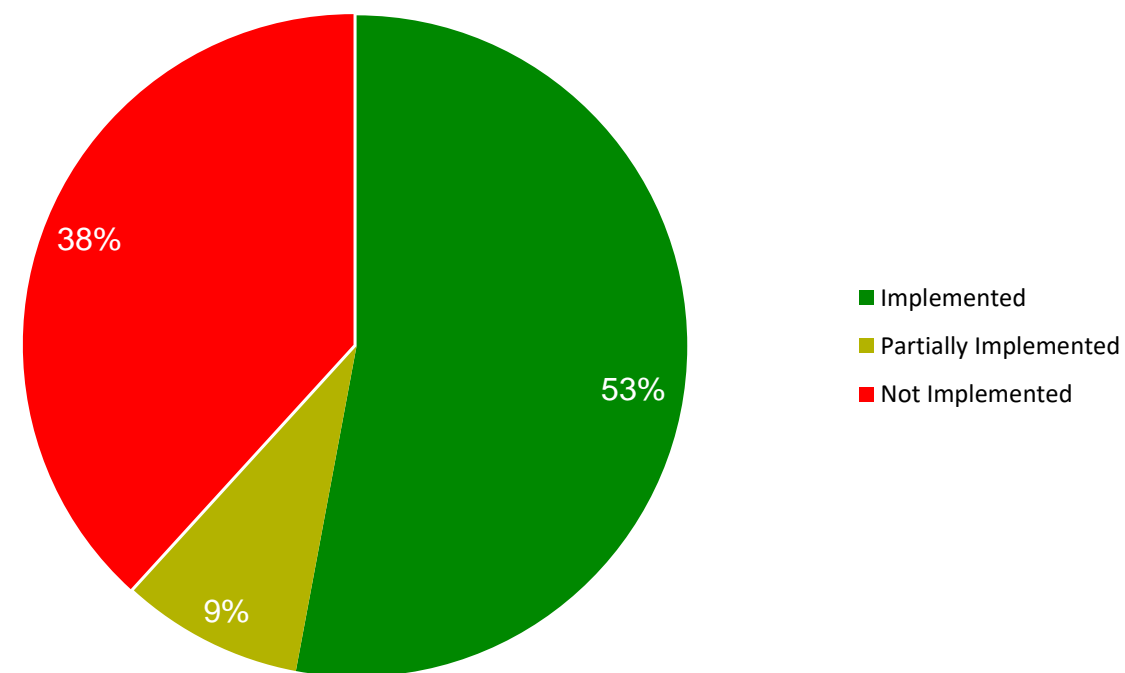
| Status | # |
|-----------------------|----|
| Implemented | 20 |
| Partially Implemented | 3 |
| Not Implemented | 11 |



CT05.01: Clarity about EC funding

ML: 

| Status | # |
|-----------------------|----|
| Implemented | 18 |
| Partially Implemented | 3 |
| Not Implemented | 13 |



Thank you

For more information, please contact:
Email: nra_admin@who.int