

10 November 2025

## Draft agenda – fourth EMA-MedTech Europe bilateral meeting

21 November 2025 - 10:00-12:00 CEST

Chair: Alberto Ganan Jimemez, Head of Committees and Quality Assurance Department

| Item | Preliminary draft agenda   | Mins            |
|------|--|-----------------|
| 1.   | Welcome and introduction   | 10:00-<br>10:10 |
| 2.   | MedTech Europe key priorities and strategy   | 10:10-<br>10:35 |
| 3.   | <ul> <li>MedTech Europe position on legislation:</li> <li>MD/IVD regulation and planned revision</li> <li>AI act and digitalisation</li> </ul>                 | 10:35-<br>11:10 |
| 4.   | <ul> <li>MedTech Europe feedback on:</li> <li>Expert Panels for orphan and paediatric</li> <li>HTAR interface with EMA and expert panels activities</li> </ul> | 11:10-<br>11:25 |
| 5.   | Update from the EMA on scientific advice activities  | 11:25-<br>11:35 |
| 6.   | Combination product regulatory pathway optimisation  | 11:35-<br>11:55 |
| 7.   | Conclusion and next steps Closure of meeting   | 11:55-<br>12:00 |

