MEDTECH MILESTONES FRAMEWORK

Innovation Maturity Level	Name	Overall Description	Innovation Maturity Level Milestones			
			Clinical	**Market/Business**	**Regulatory**	**Technology**
1	**Need**	**Insights into unmet clinical needs and available solutions**	❑ Unmet need statement ❑ Disease state characterization	❑ Needs screening & selection ❑ Existing solutions characterization	❑ Regulatory familiarization	❑ State-of-the-Art summary
2	**Idea**	**Potential solution to unmet need described, evaluated and selected**	❑ Workflow scenario ❑ Updated need statement ❑ Envisioned benefit statement ❑ Feedback from 5+ clinical stakeholders	❑ Competitive landscape ❑ Envisioned Value Proposition ❑ Key stakeholders identified ❑ Reimbursement familiarization	❑ Medical device determination (MDR in EU) ❑ Comparable identified	❑ Idea screening and selection ❑ Paper Prototype ❑ Institutional IP disclosure
3	**Proof of Concept (PoC)**	**Key component concepts validated in models and value proposition tested**	❑ Feedback from clinical stakeholders in 5+ settings ❑ Updated need statement and workflow scenario ❑ Target outcomes	❑ Competing solutions characterization ❑ Preliminary value proposition ❑ Path-to-Payment plan ❑ Stakeholder map ❑ Business protection model	❑ Preliminary regulatory classification ❑ Preliminary regulatory pathway ❑ Preliminary intended /indications for use ❑ Preliminary risk and hazard analysis	❑ Key component PoC prototypes ❑ Demonstration results ❑ Preliminary Freedom to Operate (FTO) Assessment ❑ Updated institutional IP disclosure ❑ Key in-sourcing requirements
4	**Proof of Feasibility (PoF)**	**Feasibility of whole solution demonstrated in models and in feedback from stakeholders**	❑ Feedback on users in 20+ settings ❑ Updated need statement and Use Case scenario/workflow ❑ Updated target outcomes	❑ Feedback from 5+ economic buyers ❑ Preliminary business model ❑ Development plan ❑ Key relationships identified ❑ Business advisory board	❑ Draft essential requirements checklist ❑ Draft product claims ❑ Draft instructions for use ❑ Institutional approval request(s) ❑ Submission pathway defined	❑ Product Requirement Document (PRD) ❑ "Works Like" and "Looks Like" prototypes ❑ Essential experiment results ❑ Provisional IP filing & initial FTO review ❑ Key in-sourcing plans ❑ Manufacturing/QMS plan
5	**Proof of Value (PoV)**	**The potential of the solution to work and create value for all**	❑ Feedback from 100+ users ❑ Feedback from 5+ KOLs	❑ Key management team committed ❑ Investor ready business plan	❑ Essential requirements checklist ❑ Application form to competent authority submitted	❑ "Works Like, Looks Like, Made Like" prototypes ❑ Essential technical experiments results

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		stakeholders is demonstrated	❑ Use Case/ scenarios testing with 10+ users ❑ **Animal/first in/with man experiments** ❑ Medical advisory board ❑ Clinical trial endpoints	❑ Feedback from 20+ economic buyers ❑ **Initial Seed Investment** ❑ Key relationships formalized ❑ Incorporation & Founders agreement	❑ Clinical Investigation approval(s)	❑ IP search report ❑ GMP compliant pilot manufacturing process ❑ Key in-sourcing requirements committed
6	**Initial Clinical Trials (ICT)**	**Regulated production of prototypes and collection of clinical and economic data**	☐ **Endpoints achieved in Feasibility clinical trials** ☐ Demo feedback from 25+ users ☐ Peer reviewed publication(s) submitted	☐ Value quantification ☐ Feedback from 25+ economic buyers ☐ **1st institutional investment**	☐ GDPR/HIPAA compliance ☐ Security and vulnerability certifications ☐ Data requirements confirmation ☐ Pre-submission filed	☐ cGMPs compliant manufacturing process ☐ Updated specification & experimental validation ☐ All in-sourcing licensing requirements achieved ☐ **Full IP application**
7	**Validation of Solution (VoS)**	**The solution is shown to be effective and its value to all stakeholders is validated**	❑ **Endpoints achieved in pivotal clinical trials** ❑ Peer reviewed publication(s) accepted	❑ Purchasing intent from 10+ buyers ❑ **2nd round of institutional investment**	❑ Submission of Technical file to regulatory body	❑ Quality assured process validation (cGMP) ❑ Updated specification & experimental validation
8	**Approval & Launch (A&L)**	**Institutional and regulatory approval received and sales launch**	❑ Training materials & support established ❑ Specialty medical groups review in place	❑ **Initial sales** ❑ Regionalization plans	❑ **Registration and listing** ❑ **CMS/Public Coverage and CPT/DRG code determination**	❑ Finalized cGMP production environment ❑ IP for improvements filed
9	**Clinical Use (Use)**	**The solution is used successfully in day-to-day clinical practice**	❑ Included in local practice guidelines ❑ Peer reviewed publications	❑ **Profitable sales** ❑ New markets launched	❑ Monitoring/ inspections	❑ Improvement plan ❑ **Key patents issued**
10	**Standard of Care (SoC)**	**The solution is recognised as the standard of care**	❑ Recommended practice by medical specialty	❑ Dominant market share ❑ Health economics study	❑ Product Obsolescence plan	❑ Component Obsolescence plan

For more information on the specific meaning of each of the milestones you can access:
https://gaits.org/web/medtech/guidance

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DIGITAL HEALTH MILESTONES FRAMEWORK

Innovation Maturity Level	Name	Overall Description	Innovation Maturity Level Milestones			
			Clinical	**Market/Business**	**Regulatory**	**Technology**
1	**Need**	**Insights into unmet clinical needs and available solutions**	❑ Unmet need statement ❑ Disease state characterization	❑ Needs screening & selection ❑ Existing solutions characterization	❑ Regulatory familiarization	❑ State-of-the-Art summary
2	**Idea**	**Potential solution to unmet need described, evaluated and selected**	❑ Workflow scenario ❑ Updated need statement ❑ Envisioned benefit statement ❑ Feedback from 5+ clinical stakeholders	❑ Competitive landscape ❑ Envisioned Value Proposition ❑ Key stakeholders identified ❑ Reimbursement familiarization	❑ Medical device determination (MDR in EU) ❑ Comparable identified	❑ Idea screening and selection ❑ System and module requirement specification ❑ Interface mock-ups ❑ Institutional IP disclosure
3	**Proof of Concept (PoC)**	**Key component concepts validated in models and value proposition tested**	❑ Feedback from clinical stakeholders in 5+ settings ❑ Updated need statement and workflow scenario ❑ Target outcomes	❑ Competing solutions characterization ❑ Preliminary value proposition ❑ Path-to-Payment plan ❑ Stakeholder map ❑ Business protection model	❑ Preliminary regulatory classification ❑ Preliminary regulatory pathway ❑ Preliminary intended /indications for use ❑ Preliminary risk and hazard analysis	❑ Preliminary system and software architecture ❑ Key module PoC prototypes ❑ Demonstration results ❑ Updated institutional IP disclosure ❑ Key in-sourcing requirements
4	**Proof of Feasibility (PoF)**	**Feasibility of whole solution demonstrated in models and in feedback from stakeholders**	❑ Feedback on users in 20+ settings ❑ Updated need statement and Use Case scenario/workflow ❑ Updated target outcomes	❑ Feedback from 5+ economic buyers ❑ Preliminary business model ❑ Development plan ❑ Key relationships identified ❑ Business advisory board	❑ Draft essential requirements checklist ❑ Draft product claims ❑ Draft instructions for use ❑ Institutional approval request(s) ❑ Cyber security plan ❑ Submission pathway defined	❑ Product Requirement Document (PRD) ❑ Software and hardware architecture ❑ "Works Like" prototype ❑ Essential experiment results ❑ Provisional IP filing & initial FTO review ❑ Key in-sourcing plans ❑ Risk mitigation and interoperability plan
5	**Proof of Value**	**The potential of the solution to work and create value for all**	❑ Feedback from 100+ users ❑ Feedback from 5+ KOLs	❑ Key management team committed ❑ **Investor ready business plan**	❑ Essential requirements checklist	❑ "Works Like, Looks Like, prototypes ❑ Essential technical experiments results

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	(PoV)	**stakeholders is demonstrated**	❑ Medical advisory board ❑ Clinical pilot ❑ Clinical trial endpoints	❑ Feedback from 20+ economic buyers ❑ Initial Seed Investment ❑ Key relationships formalized ❑ Incorporation & Founders agreement	❑ Application form to competent authority submitted ❑ Clinical Investigation approval(s) ❑ Protected Health Information (ePHI) plans	❑ Interoperability validation ❑ cGMP medical software and production environments (s) ❑ Key in-sourcing requirements committed
6	**Initial Clinical Trials (ICT)**	**Regulated production of prototypes and collection of clinical and economic data**	❑ **Endpoints achieved in Feasibility clinical trials** ❑ Demo feedback from 25+ users ❑ Peer reviewed publication(s) submitted	❑ Value quantification ❑ Feedback from 25+ economic buyers ❑ **1st institutional investment**	❑ GDPR/HIPAA compliance ❑ Security and vulnerability certifications ❑ Data requirements confirmation ❑ Pre-submission filed	❑ Updated specification & experimental validation ❑ All in-sourcing licensing requirements achieved ❑ Full IP application
7	**Validation of Solution (VoS)**	**The solution is shown to be effective and its value to all stakeholders is validated**	❑ **Endpoints achieved in pivotal clinical trials** ❑ Peer reviewed publication(s) accepted	❑ Purchasing intent from 10+ buyers ❑ **2nd round of institutional investment**	❑ Submission of Technical file to regulatory body	❑ Quality assured process validation (cGMP) ❑ Updated specification & experimental validation
8	**Approval & Launch (A&L)**	**Institutional and regulatory approval received and sales launch**	❑ Training materials & support established ❑ Specialty medical groups review in place	❑ Initial sales/deployment ❑ Regionalization plans	❑ **Registration and listing** ❑ **CMS/Public Coverage and CPT/DRG code determination**	❑ Finalized cGMP production environment ❑ Regionalization requirements
9	**Clinical Use (Use)**	**The solution is used successfully in day-to-day clinical practice**	❑ Included in local practice guidelines ❑ Peer reviewed publications	❑ **Profitable sales** ❑ New markets launched	❑ Monitoring/ inspections	❑ Improvement plan ❑ Regionalization implemented
10	**Standard of Care (SoC)**	**The solution is recognised as the standard of care**	❑ Recommended practice by medical specialty	❑ Dominant market share ❑ Health economics study	❑ Product Obsolescence plan	❑ Component Obsolescence plan

For more information on the specific meaning of each of the milestones you can access:
https://gaits.org/web/-digital-medicine/guidance

BIOMARKERS DIAGNOSTICS MILESTONES FRAMEWORK

Innovation Maturity Level	Name	Overall Description	Innovation Maturity Level Milestones			
			Clinical	**Market/Business**	**Regulatory**	**Technology**
1	**Need**	**Insights into unmet clinical needs and available solutions**	❑ Unmet need statement ❑ Disease state characterization	❑ Needs screening & selection ❑ Existing solutions characterization	❑ Regulatory familiarization	❑ State-of-the-Art summary
2	**Idea**	**Potential solution to unmet need described, evaluated and selected**	❑ Clinical Workflow scenario ❑ Updated need statement ❑ Envisioned benefit statement ❑ Feedback from 5+ clinical stakeholders	❑ Competitive landscape ❑ Envisioned Value Proposition ❑ Key stakeholders identified ❑ Reimbursement familiarization	❑ Medical device determination (MDR in EU) ❑ Comparable identified	❑ Idea screening and selection ❑ Preliminary Target Product Profile ❑ Biological mechanism of action identified ❑ Institutional IP disclosure
3	**Proof of Concept (PoC)**	**Key component concepts validated in models and value proposition tested**	❑ Feedback from clinical stakeholders in 5+ settings ❑ Updated need statement and workflow scenario ❑ Target outcomes	❑ Competing solutions characterization ❑ Preliminary value proposition ❑ Path-to-Payment plan ❑ Stakeholder map ❑ Business protection model	❑ Preliminary regulatory classification ❑ Preliminary regulatory pathway ❑ Preliminary intended /indications for use	❑ **Key mechanism of action validated** ❑ Updated Target Product Profile (TPP) ❑ Preliminary Freedom to Operate (FTO) Assessment ❑ Updated institutional IP disclosure ❑ Key in-sourcing requirements
4	**Proof of Feasibility (PoF)**	**Feasibility of whole solution demonstrated in models and in feedback from stakeholders**	❑ Feedback on users in 20+ settings ❑ Updated need statement and Use Case scenario/workflow ❑ Updated target outcomes	❑ Feedback from 5+ economic buyers ❑ Preliminary business model ❑ Development plan ❑ Key relationships identified ❑ Business advisory board	❑ Draft essential requirements checklist ❑ Draft product claims ❑ Draft instructions for use ❑ Institutional approval request(s) ❑ Submission pathway defined	❑ Updated Target Product Profile (TPP) ❑ “Works Like” and “Looks Like” packaging prototypes ❑ Essential experiment results ❑ Provisional IP filing & initial FTO review ❑ Key in-sourcing plans ❑ Manufacturing/QMS plan
5	**Proof of Value (PoV)**	**The potential of the solution to work and create value for all stakeholders is demonstrated**	❑ Feedback from 100+ users ❑ Feedback from 5+ KOLs ❑ Animal/first in/with man experiments ❑ Medical advisory board	❑ Key management team committed ❑ Investor ready business plan ❑ Feedback from 20+ economic buyers ❑ Initial Seed Investment ❑ Key relationships formalized	❑ Essential requirements checklist ❑ Application form to competent authority submitted ❑ Clinical Investigation approval(s)	❑ "Works Like, Looks Like, Made Like”, “Made Like” prototypes ❑ Updated TPP & Essential technical experiments results ❑ IP search report

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			❑ Clinical trial endpoints	❑ Incorporation & Founders agreement		❑ cGMP compliant pilot manufacturing process ❑ Key in-sourcing requirements committed ❑ Conference/poster session/paper submitted
6	**Initial Clinical Trials (ICT)**	**Regulated production of prototypes and collection of clinical and economic data**	☐ **Endpoints achieved in Feasibility clinical trials** ☐ Peer reviewed publication(s) submitted	☐ Value quantification ☐ Feedback from 25+ economic buyers ☐ **1st institutional investment**	☐ Data requirements confirmation ☐ Pre-submission filed	☐ cGMPs compliant manufacturing process ☐ Updated TPP & experimental validation ☐ All in-sourcing licensing requirements achieved ☐ **Full IP application**
7	**Validation of Solution (VoS)**	**The solution is shown to be effective and its value to all stakeholders is validated**	❑ **Endpoints achieved in pivotal clinical trials** ❑ Peer reviewed publication(s) accepted	❑ Purchasing intent from 10+ buyers ❑ **2nd round of institutional investment**	❑ Submission of Technical file to regulatory body	❑ Quality assured process validation (cGMP) ❑ Updated TPP & experimental validation
8	**Approval & Launch (A&L)**	**Institutional and regulatory approval received and sales launch**	❑ Training materials & support established ❑ Specialty medical groups review in place	❑ **Initial sales** ❑ Regionalization plans	❑ **Registration and listing** ❑ **CMS/Public Coverage and CPT/DRG code determination**	❑ Finalized cGMP production environment ❑ IP for improvements filed
9	**Clinical Use (Use)**	**The solution is used successfully in day-to-day clinical practice**	❑ Included in local practice guidelines ❑ Peer reviewed publications	❑ **Profitable sales** ❑ New markets launched	❑ Monitoring/ inspections	❑ Improvement plan ❑ Key patents issued
10	**Standard of Care (SoC)**	**The solution is recognised as the standard of care**	❑ Recommended practice by medical specialty	❑ Dominant market share ❑ Health economics study	❑ Product Obsolescence plan	❑ Component Obsolescence plan

For more information on the specific meaning of each of the milestones you can access:
https://gaits.org/web/biomarker-diagnostic/guidance

PURE BIOTECH MILESTONES FRAMEWORK

Innovation Maturity Level	Name	Overall Description	Innovation Maturity Level Milestones			
			Clinical Validation	**Market/Business**	**Technology**	**Regulatory**
1	**Need**	**Insights into unmet medical needs and available solutions**	❑ Unmet needs defined ❑ Disease state characterized ❑ Biological Mechanism of action identified ❑ Cellular disease pathway identified and described	❑ Deficiency in existing solutions identified ❑ Competitive landscape identified (academic, in pre-clinical/clinical development/commercial) ❑ Market Assessment/ Initial description of target population and its biological characteristics	❑ Molecular target/s identified ❑ Approaches for pharmacological targeting searched and identified ❑ Proposed technological modality explored (small molecule, antisense oligo, antibody, gene therapy, cell therapy, repurposed/repositioned product, etc) ❑ Initial patent landscape reviewed and patentability assessment done ❑ Initial institutional "Idea" (IP) disclosed to employer	❑ Clinical trials in the indication identified for reference trial design and timelines (ie. clinicaltrials.gov landscape)
2	**Idea**	**Potential solution to unmet need described, evaluated and selected**	❑ Biological pathway studied and intervention/perturbation approaches developed ❑ Biotechnological platform characterized and potential use cases developed ❑ Proposed patient population (SOP) defined including genetic or other bio markers (biochemical, cellular, imaging/digital/electrophysiological) if possible	❑ Envisioned Value Proposition ❑ Target Product Profile – (TPP) first iteration ready ❑ Identified complementary IP ❑ Initial dialogue with potential stakeholders (Pharma, VC, Corporate VC, Incubators) with positive feedback ❑ Investor ready business plan (milestone-based development plan R&D)	❑ Technological modality selected ❑ Mechanism of action of target group elucidated in vitro ❑ Compound starting point, screening and selection scheme planning done ❑ Compound selection assay development initiated ❑ Biological hypothesis and pharmacological hypothesis formulation identified ❑ For repurposed molecules not in the market (ie, shelved big pharma products) explore availability of clinical dossier from originator ❑ In licensing discussions with owners of IP have started (host institute, exclude originators of repurposed products until method of use patent is filed) ❑ Statement of employer issued ❑ Prior art has been assessed (Freedom to Operate analysis) and patentability of the innovation is confirmed by a patent attorney ❑ Translational models (patient sample based or in-vivo) identified	❑ Regulatory Familiarization started ❑ For rare disease, paediatric or cell & gene therapy: Consulted the regulatory roadmap pathways if applicable and familiarized with alternative pathways
3	**Proof of Concept (PoC)**	**Key component concepts validated in models and value proposition tested**	❑ Mechanistic and therapeutic hypothesis validated in genetic/metabolic models and/or patient derived cells – go/no-go decision ❑ For repurposed products: Proof of concept in relevant in vivo model obtained with repurposed candidate with favourable HED (prospective dose in humans below doses already tested or within safety margins)	❑ Business model defined - Value inflection points identified and preliminary value creation plan defined ❑ **Seed investment secured** ❑ Stakeholder map defined ❑ Scientific Advisory Board recruited ❑ Communication & public dissemination plan established (ie: thesis, papers & communications in relevant scientific forums) ❑ Killer experiment identified	❑ Initial hits/compound candidates synthesized and evaluated ❑ Initial pharmacology analysis – efficacy, safety, PK and bioavailability in rodent/relevant animal model (if applicable) ❑ **IP strategy defined and first IP filing initiated** ❑ For non-generic repurposed products: started negotiations with originators to access IP & clinical development - enabling data (updated IPMD, only if robust IP is filed) ❑ For biological or gene-therapy products: manufacturing roadmap and costing estimates defined ❑ If platform – initial creation and testing of platform modules and building blocks	❑ Preliminary regulatory pathway defined ❑ For advanced therapies or paediatric diseases: scientific advice / pre-IND meeting or equivalent feedback required
4	**Proof of Feasibility (PoF)**	**Feasibility of whole solution demonstrated in models and in feedback from stakeholders**	❑ **Hit/lead compounds efficacy and potency in animal model or patient derived model validated**	❑ Deal and market benchmark cases identified ❑ Collection of economic data compared to SoC initiated (e.g. validating beach-head market)	❑ Feasibility proven in essential experiment – safety, bioavailability, PK-PD. **For gene therapy product: biodistribution data in big animal (monkey, pig) provided** ❑ **Composition of matter IP filed** - IP search report is promising	❑ Drafted essential requirements checklist ❑ Retrospective study performed if data available

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			❑ For biologicals or gene-therapy products: efficacy data in animal model obtained with regulatory compliant final candidate. ❑ Updated need description with confirmation of target patient population ❑ Proposed treatment scheme developed (preventive/therapeutic acute/chronic etc.) ❑ Clinical KOLs consulted in adhoc preparatory meetings, positive engagement and commitment to participate in clinical trials ❑ Draft clinical development plan completed (Incl. target population and line of care and target regimen) ❑ CRO screening initiated ❑ Potential biomarkers identified	❑ Pricing estimates validated through third party independent primary research ❑ Target Product Profile – (TPP) refined	❑ In-licensing or round-A discussions are in progress to mutual satisfaction ❑ Manufacturing expertise initial conversations	❑ Submission pathway defined and validated by a regulatory body (scientific advice in EMA or official pre-IND meeting for FDA) ❑ Biomarker validation study approved, if needed
5	**Proof of Value (PoV)**	**The potential of the solution to work and create value for all stakeholders is demonstrated**	❑ **Clinical lead candidate validated in clinically relevant animal model** ❑ Clinical advisory board recruited ❑ **Clinical protocol completed** ❑ Clinical CRO selected ❑ Clinical endpoints defined and validated vs. competition – clinical target efficacy value defined	❑ Peer reviewed publication(s) accepted - preclinical (consider strategic perspective) ❑ Collection of economic data compared to SoC completed ❑ Series A/B financing completed ❑ Advanced stakeholder partnering discussions ongoing ❑	❑ Minimum viable product (MVP) ready – clinical lead optimized ❑ CMC development started in parallel to IND-enabling safety tox preclinical package. ❑ Pharmaceutical development started ❑ **Full IP application – freedom to operate positive opinion.** ❑ In-licensing of essential IP is completed (For Repurposed products: including third party IND-enabling clinical data)	❑ Application form to competent authority submitted ❑ Submission data package defined (essential Requirements checklist) ❑ IND/CTA meeting scheduled/performed ❑ **IND/CTA approved** ❑ Clinical Investigation approval(s) achieved (Ethical committees/IRBs)
6	**Initial Clinical Trials (ICT)**	**Regulated production of prototypes and collection of clinical and economic data**	❑ **Endpoints Successfully achieved in clinical safety/efficacy trials (Phase 1/2 clinical trials)**	❑ Pharmacoeconomics analysis performed ❑ Advanced discussions for next steps with investors and stakeholders (pharma) ❑	❑ Pre-clinical development of additional portfolio products ❑ Long term safety studies if appliable ❑ Potential formulation updates for lead product explored	❑ Additional data submitted ❑ Scientific advise / FDA consultation to validate phase II design
7	**Validation of Solution (VoS)**	**The solution is shown to be effective and its value to all stakeholders is validated**	❑ **Endpoints Successfully achieved in clinical efficacy trials (Phase 2a/2b)** ❑ Preparation of Phase 3 clinical studies ❑ Peer reviewed publication(s) accepted -clinical ❑ Additional indications explored ❑ Biomarker /companion diagnostic validated (if applicable)	❑ **Collaboration in place with Pharma / multiple pharma's** ❑ Gearing up partnerships and development of new pipeline products ❑ Financing efforts in place for next round (private or public)	❑ Pharmaceutical development (final commercial formulation) completed ❑ Carcinogenicity studies if applicable. ❑ For biological products: full specs validated with regulatory bodies ❑ For immunological products: potency test validated with regulatory bodies ❑ Manufacturing of clinical batch for later phase clinical studies ❑ **Development of new products on the pipeline – IP submitted**	❑ Additional data submitted ❑ Proactive scientific advise / FDA consultation to validate phase III strategy
8	**Approval & Launch (A&L)**	**Institutional and regulatory approval received and sales launch**	❑ Specialty medical groups review in place ❑ KOL's and clinical leads recruited and supportive ❑ **Endpoints Successfully achieved in Phase 3 clinical studies** ❑ Post marketing trial initiated	❑ **Initial sales achieved** ❑ Expanding sales activities	❑ Three manufacturing batches validated ❑ Alternative manufacturers identified ❑ Manufacturing capability expansion planned	❑ **Registration approval and listing** ❑ CMS/Public Coverage and CPT/DRG code determination obtained
9	**Clinical Use (Use)**	**The solution is used successfully in day-to-day clinical practice**	❑ Included in practice guidelines ❑ Additional data published in peer reviewed journals	❑ Profitable sales achieved ramp-up ❑ New markets launched	❑ Key patents issued. ❑ Competition monitored ❑ Alternative manufacturing sites validated (it may take over 2 years)	❑ Monitoring/ inspections
10	**Standard of Care (SoC)**	**The solution is recognised as the standard of care**	❑ Recommended practice by medical specialty	❑ Dominant market share status ❑ Operating margin profile achieved	❑ Patents issued - Patent Lifecycle Management	❑ Health economic studies carried

Patient Population (SOP)- Standard operating procedures

KOL- Key Opinion Leader

HED- Human Equivalent Dose

PK/PD Modeling- pharmacokinetic/pharmacodynamic modeling

CRO- Contract research organization

CMC- Chemistry, manufacturing, and control

PCT- Patent Cooperation Treaty

IRB- Institutional Review Board

CTA- Clinical Trial Application

IND- Investigational New Drug

CMS- Centers for Medicare & Medicaid Services

CPT- Current Procedural Terminology

DRG- Diagnosis-related group