# 加速医药创新转型，赋能健康中国建设新机遇

罗氏集团
全球首席执行官
施万博士

## 摘要

随着经济社会的发展，人民健康被提升到优先发展的战略地位。中国政府提出“健康中国”战略，推进从“以治病为中心”向“以人民健康为中心”的转变。在支持健康中国战略实施和推动社会经济的高质量发展过程中，下述两点扮演重要角色：

（1）医疗数据应用

信息技术的发展让世界各国认识到，数据在解决棘手医疗健康问题上有巨大潜力。战略性地使用成规模、有意义的数据（meaningful data at scale, MDAS）和先进的数字化医学技术，可加快转型复杂重症（如恶性肿瘤）疾病管理模式，实现早筛、早诊、早治，并鼓励转变医疗资源使用的模式。规范使用数据要素将成为医疗健康行业新的增长点，2020 年全球新冠疫情的流行更凸显了大数据在医疗健康领域的重要性。目前，中国已出台一

系列政策法规，推动医疗健康数据应用、释放数据潜力；并在全球数字化转型中处于领先地位，为数字化医疗提供独特的发展平台，便于医疗健康与大数据、人工智能等先进技术深度融合。然而，践行过程中也面临数据权属、质量、安全及释放数据价值等方面的挑战。为进一步发挥数据要素在医疗健康行业中的价值，罗氏集团建议以下政策或行动：

- 建立以患者为中心的一体化医疗健康数据库；
- 考虑打造动态调整、分级分类数据管理机制，合理应用数据并保护个人隐私；
- 充分挖掘信息技术和医疗数据潜力，创新数据应用场景；
- 提升医务工作者对以“患者为中心，数据为驱动”医疗健康体系概念的认知，增强患者参与度。

（2）生物医药产业创新

医药创新对提升人民健康至关重要，特别是在应对疑难重症等高需求方面。中国已将生物医药产业创新纳入顶层发展战略。近年来，中国在支持临床研究、加强监管审批、提高支付保障能力上取得了长足进步。由于生物创新研发资金投入大、周期长、风险高，可以考虑建立合理的创新激励机制，鼓励企业在高风险和高需求的医疗领域长期探索、坚持创新。政策主导与市

场驱动相结合的市场环境将为中国患者带来更多突破性疗法，实现全民健康覆盖。罗氏集团建议考虑的关键领域包括：

- 持续完善以政策为驱动的市场环境，提供以创新为核心、奖励创新的政策生态环境，例如加强改进药品评审制度；
- 完善医保支付政策，充分考虑药物创新价值，探索风险共担的创新支付方式。

作为数字化医疗的领军企业，罗氏集团的业务遍及全球 100 多个国家，并积累了丰富的行业经验。植根中国 90 多年来，罗氏集团始终践行对中国的长期承诺，并致力于成为中国迈向全球生物医药创新前列的差异化合作伙伴。罗氏集团将把握中国医药健康数据和生物医药产业创新发展的新机遇，分享研发、市场准入创新的经验和行业洞察，推动完善政策和市场环境，利用贯穿其业务的集成的、端对端的能力持续投入并支持生物医药创新产业蓬勃发展，以满足中国乃至全球患者的需求，全方位推动实现“健康中国 2030”目标。

## 一、介绍：战略性聚焦医疗健康数据应用与生物医药产业创新发展，共筑健康中国新机遇

***改革开放四十多年以来，中国经济与社会均实现了跨越式发展，取得有目共睹的巨大成就。***其间，中国经济创造了多个里程碑，消除了绝对贫困，是 2020 年全球唯一实现经济正增长的主要经济体。全球第二高的研发投资总量彰显出中国正提升发展的协调性和可持续性，逐步迈向创新型国家。

***中国共产党第十八届五中全会首次将人民健康提升至优先发展的战略地位。***2016 年 10 月中共中央、国务院颁布《“健康中国 2030”规划纲要》，启动“健康中国”建设，并明确指出“健康中国”是关系中国现代化建设全局的重大战略任务。《纲要》强调以预防为主，推动卫生发展模式从“以治病为中心”向“以人民健康为中心”转变。

***医疗健康数据应用及生物医药产业创新将为中国医药健康产业发展带来崭新的机遇。***信息技术的升级迭代加速医疗健康产业蓬勃发展，也将进一

步提升中国在生物医学前沿的创新能力。战略性聚焦医疗健康数据应用与生物医药产业创新的发展，将助力中国跻身全球医药产业创新第一梯队，更加精准地满足人民群众多层次、多样化、个性化的健康需求。

***罗氏承诺以行业经验及先进的医疗技术，支持早日实现健康中国 2030 战略。***自 1896 年创立于瑞士以来，罗氏集团始终走在医疗技术创新的前沿，在抗肿瘤、抗感染、抗病毒、移植、风湿免疫等关键疾病领域，为人民健康保驾护航。2020 年，罗氏集团一跃成为全球最大的生物技术公司，研发投入超过 130 亿美元，位于全球第一。凭借制药和诊断两大业务全球领先的独特优势，和在基因测序等新兴业务领域上的并购投入，罗氏集团已成为个体化医疗领域的领导者。

作为最早开拓中国市场的商业伙伴，罗氏集团见证了中国惊人的发展成就，并率先在中国建成了完整的医药价值产业链。展望未来，罗氏集团将继续深度参与中国医疗产业发展，助力中国的创新发展。为早日实现“健康中国”的美好愿景，罗氏集团已积极开展各类疾病防治领域的倡议与实践行动。在近日由健康中国行动推进委员会办公室指导、人民网•人民健康主办

的 2021 年全国两会“健康中国人”系列圆桌论坛中，罗氏集团倡议社会多方携手关注癌症防治，共筑肿瘤筛查、诊断、治疗闭环。

## 二、医疗健康数据应用将为健康中国建设提供新机遇

***信息技术日新月异，世界各国纷纷认识到数据作为生产要素对医疗健康产业发展的战略作用，二者有机融合将驱动数字化医疗快速发展。***据麦肯锡报告《医疗行业的大数据革命》预测，美国医疗领域的数字化应用帮助减少 12%~17%的医疗支出。随着大数据与医疗系统的深度融合，其规模效益将在药物研发、临床诊疗、健康管理、医疗体系等各个环节体现，并大幅提升医疗系统效率。

***后疫情时代，加快释放数据要素价值成为全球发展趋势之一。***2020 年的新冠疫情暴露出国家和城市在社会治理能力和公共健康体系的一系列问题。作为主要应对手段之一，大数据在医疗健康领域发挥了至关重要的作用。罗氏作为数字化医疗领域的先驱，已在多国推出合作应用程序。新冠疫

情期间，罗氏携手加拿大等国多家企业共同打造公开可用的疫情数据库。得益于成规模有意义数据（meaningful data at scale, MDAS）在诊断领域的合理应用，罗氏通过先进的数据诊断解决方案，为科学防疫做出积极贡献。在中国政府的引领与合作中，罗氏将积极探索数据应用及其带来的新机遇，助力“健康中国”实施。

### 2.1 国际上，已有国家开始数字化医疗领域的积极探索与布局

丹麦国家生物银行[1]由科学、创新和高等教育部合作共同建立[2]，收集了超过 1000 万个不同诊断类别的生物样本，并***与保存国家人口医学记录的民事登记系统相连接，帮助研究者获取患者预后康复、健康管理等全周期健康数据。***生物银行不仅助力该国的医疗产业创新，同时在临床实践中为疾病预防、治疗及病程跟踪提供便利。

[1] 丹麦国家生物银行.Danish National Biobank [A/OL].(2020)[2020-07-17] https://www.danishnationalbiobank.com

[2] 丹麦国家生物银行. Information About the Danish National Biobank [A/OL].(2019-09)[2020-07-17] https://www.danishnationalbiobank.com/-/media/arkiv/subsites/dnb-uk/information-about-the-danish-national-biobank.pdf?la=en

英国卫生部发起十万人基因组项目，***采集 10 万个来自癌症及罕见病患者的基因组进行测序，并收集患者临床数据及儿童时期病历数据***[3]。2017 年以来，该项目通过基因组学数据，使癌症和罕见病领域学术论文发表数量逐年增加[4]。此外，项目的研究成果也被应用于当地医务人员培训，帮助医务人员了解患者需求和提升医疗服务的质量[5]。

## 2.2 近年来，中国在医疗健康数据应用探索方面取得了有效进展

***中央政府出台系列政策法规，促进医疗健康数据应用发展。***国务院于 2016 年出台了《关于促进和规范健康医疗大数据应用发展的指导意见》，将大数据与医疗健康领域融合发展提升至国家战略高度。此后，国家卫生健康委员会发布《“十三五”全国人口健康信息化发展规划》等政策，从夯实基础建设、深化数据应用、创新模式发展等方面，大力推进建设健康医疗大数据服务体系。2020 年 4 月，中共中央国务院在《关于构建更加完善的要素市场化配置的体制机制的意见》中首次明确“数据”作为新型生产要素的

[3] 英格兰基因组组织. Genomics England [A/OL].(2020)[2021-03-02] https://www.genomicsengland.co.uk
[4] 英格兰基因组组织. Publications [A/OL].(2020)[2021-03-02] https://www.genomicsengland.co.uk/about-gecip/publications/
[5] 英格兰基因组组织. Delivering the Project [A/OL].(2020)[2021-03-02] https://www.genomicsengland.co.uk/about-genomics-england/the-100000-genomes-project/

战略地位，鼓励加快培育数据要素市场，同时“推动完善适用于大数据环境下的数据分类分级安全保护制度”。同年 5 月，国务院提出“建立数据资源清单管理机制，完善数据权属界定、开放共享、交易流通等标准和措施”。

***目前中国已建立了一批分级、分类、不同应用主题的数字化平台***，在业务、服务、科研等方面，初步开放医疗健康信息化、数据化共享，并在疫情期间发挥了积极作用。国家基因组科学数据中心于 2019 年 6 月成立，致力于研发生物多样性与健康大数据交汇、共享、管理平台，组建基因组科学数据中心。疫情期间，其新型冠状病毒信息库汇集发布了 56036 条 COVID-19 病毒序列、208 条临床信息[6]。

### 2.3 中国的医疗健康数据应用有待进一步完善与发展

***尽管中国在医疗健康数字化应用中取得了诸多成就，其进一步发展仍面临重重困境。***MDAS 共享及应用中存在的数据权属、质量、安全以及价值释放等问题（详述见 2.3.1-2.3.3），值得政府与行业共同探索解决。

[6] 浙江数字医疗卫生技术研究院. imit 白皮书第十七期：健康医疗数据共享[R/OL].（2020）[2021-03-02] http://www.imit.org.cn/index.php?g=&m=article&a=index&id=333&cid=11

### 2.3.1 数据权属

***数据作为新型生产要素，与土地、资本、劳动力等生产要素一样，涉及权属问题***。数据权属从理论上没有统一、完整、通行的定义，从法律上也并未获得明确界定。明确数据权属是一项基础性工作，在充分保护数据所有者和相关利益方权益的前提下，才能实现数据的高效流通。

***中国已有地方开始尝试不同方法管理 MDAS 权属。***上海率先在 2019 年出台了《上海市公共数据开放暂行办法》，将公共数据的范畴界定为公共管理和服务机构在履职过程中所收集和产生的数据。同时允许个体[7]提交证据，中止可能侵害其隐私的公共数据的开放[8]。深圳近期发布的《深圳经济特区数据条例（征求意见稿）》将公立医疗机构收集的医疗健康数据从制度上被确立为国有资产[9]，并规定自然人对其被收集的数据拥有知情权及提供数据

[7] 个体：自然人，法人和非法人组织
[8] 上海市政府. 上海市公共数据开放暂行办法 [A/OL].(2019-08-29)[2021-03-02] http://www.shanghai.gov.cn/nw2/nw2314/nw2319/nw2404/nw48155/nw48156/u26aw62825.html
[9] 深圳市政府.深圳经济特区数据条例 [A/OL].(2020-07-15)[2021-03-02] http://sf.sz.gov.cn/hdjlpt/yjzj/answer/5748

的决定权。与此同时，深圳市卫健委正在组建健康医疗大数据科研分析平台，未来或将向机构及个人开放数据使用权限。[10]

### 2.3.2 数据质量

医疗数据繁多而复杂。只有数据质量足够高，数据分析方法论足够严谨，才能高效助力药物研发、规范监管和临床治疗。

***目前在健康领域，数据质量问题较为严峻。***数据使用者，如科研人员和监管人员，出于不同分析目的，对数据质量存在不同维度的诉求[11]。但总体而言，目前大部分真实世界数据质量无法满足使用者需求，以纵向数据[12]收集不足尤甚。传统数据库中，医疗数据通常以分散或不连贯的形式存在，而纵向数据，可更系统地用于临床路径设计评估，药物优化和疾病管理，并有力支持临床决策的疗效影响评估。

[10]中国政府采购网. 深圳市医学信息中心深圳市健康医疗大数据科研分析平台（一期）中标公告[A/OL].(2020-07-15)[2019-09-11]
http://www.ccgp.gov.cn/cggg/dfgg/zbgg/201909/t20190911_12880660.htm
[11] 不同维度，如临床相关性、准确性、完整性、透明性及可扩展性等
[12] 数据纵向性（纵向数据），一般指在一段相对长的时间内收集到的个体内部变化和个体间变化数据。

### 2.3.3 数据安全和充分释放数据价值

随着数字化不断发展，个人隐私问题成为社会关注的焦点。多国已出台政策措施应对这一挑战。例如，欧盟于 2018 年出台《一般数据保护条例》（GDPR），强调个人信息保护的知情同意原则。任何有关存储、处理或发布个人数据的行为都必须获得数据主体的知情同意。澳大利亚政府出台《*个人健康记录（MHR）数据二次使用指导框架*》，要求成立数据管理委员会对数据申请者进行审核，保护患者数据隐私。

***目前，中国也开始逐步完善医疗健康数据安全相关管理规定。***2019 年，国务院发布《数据安全管理办法（征求意见稿）》，针对利用网络收集、存储、传输、处理、使用数据等行为，以及数据安全保护和监督管理等方面做出框架性规定。此外，《*信息安全技术健康医疗信息安全指南*》也在制订中，将针对医疗数据典型使用场景及相应管理流程提出详细的安全措施建议。中国政府可在既有基础上，借鉴国际经验，探索制定一套完善的医疗数据管理制度。

## 2.4 政策建议

### 2.4.1 优化顶层设计，建立以患者为中心的一体化医疗健康数据库

***打通不同领域数据库壁垒，整合多方资源，是进一步释放 MDAS 潜在价值的关键。***中国政府可鼓励地方先行试点，探索打通各类健康数据资源，链接电子病历、基因组数据、生物样本、健康管理档案等数据，并将可穿戴设备等创新数据引入，建立以患者为中心的一体化医疗健康数据库，以高质量数据提升健康体系运作效率，节省社会成本。

### 2.4.2 建立动态调整、分级分类的数据管理机制

***考虑到医疗健康数据的敏感性，海量数据的集中存储和管理为数据管理带来极大挑战。***为合理应用数据并保护个人隐私，试点地区可考虑探索动态调整、分级分类的数据管理机制，从而地方及中央政府可更有力地对不同主体数据访问权限进行管控和监督，降低非法访问或滥用数据的风险。在此基础上，还可融入公共卫生的应急响应机制，及时发布与疫情相关的医疗数据，助力疫苗和新药研发，开展流行病学调查，落实相关隔离方案。

***依托数据管理机制，地方及中央政府还可探索向不同产业开放不同类型数据。***这一机制将鼓励医药相关产业发挥其自有优势，保护患者个人隐私，进一步探索产业融合新方向。

### 2.4.3 鼓励多方协同发力，充分挖掘信息技术和医疗数据潜力，创新数据应用场景

在达成高质量数据收集和管理目标的基础上，还需多方协同发力，充分利用信息技术，实现对数据的深度分析。

***利用新技术和大数据进行精准化肿瘤药物研发，更好地满足患者个性化健康需求。***现代医药技术的开发，特别是肿瘤与罕见病等领域，鲜少由一个机构独立实现；不同领域、产业与公司间的协同合作将持续推动技术进步。中国政府可鼓励不同类型的机构探索基于数据共享应用的创新型伙伴关系，共同研发满足患者需求的先进治疗方案。

***鼓励医疗机构应用先进的信息化分析技术，推动临床决策支持系统（CDSS）升级发展，提升诊疗水平和质量，改善患者体验。***通过创新信息

技术，海量的临床数据可转化为指导实际操作的信息，为医务人员提供决策支持。CDSS 帮助医生超越自身经历与学识局限，借助大量研究结果和以往实践经验，为患者设计最佳诊疗方案。

### 2.4.4 提升医务工作者对以“患者为中心，数据为驱动”医疗健康体系概念的认知，增强患者参与度

***医务人员是医疗服务的主力军，而患者是医疗健康体系的中心，激励双方共同参与构建“以患者为中心”的生态体系至关重要。***中国政府可尝试采取多种举措，促进医患双方协作，共助医疗健康体系发展升级。例如，加深医务人员对“患者为中心，数据为驱动”理念的认识、普及与推广；鼓励患者参与，实现患者赋权，让患者真正从数字化中获益。

## 2.5 罗氏贡献

***罗氏在管理、融合、分析医疗数据方面具有全球领先的专业实力和行业经验，愿助力中国政府实现健康中国战略。***

***罗氏打造了全球首个癌症患者临床基因组数据库。***罗氏依托旗下 Foundation Medicine Inc.（FMI）与 Flatiron Health 通过整合不同类型的数据，携手打造了全球首个打通癌症患者基因组数据和临床数据的数据库。该数据库既包含人口统计学、用药、诊断、肿瘤转移日期、用药史、医疗检查结果等临床数据，也涵盖了肿瘤基因组分析、基因组改变、样本和生物标记物在内的基因组数据。该数据库拥有海量高质量数据，将加速实现精准医疗，助力高效临床决策。

***罗氏在中国积极实践肿瘤个体化医疗。*** 2018 年 4 月，罗氏及其控股公司 FMI 与中国迪安合作推出国内首个针对实体肿瘤患者的全面基因组测序分析服务 FoundationOneCDx（F1CDx）。F1CDx 检测呈现的全面基因组图谱分析报告可为医生治疗决策提供患者全面分子信息，帮助医生有针对性地制定癌症治疗和预防计划。F1CDx 的应用将有望建立中国肿瘤大数据，设立中国肿瘤个体化诊疗新标准，为癌症预防及诊疗提供有效支持。

植根中国多年，罗氏非常荣幸参与到健康中国行动中，全面分享罗氏在癌症早筛、早诊、早治的全球经验和先进的生物技术解决方案，助力实现健康中国战略宏伟蓝图。

## 三、生物科技产业创新发展将为健康中国建设带来新机遇

***习近平在十八届五中全会上将创新提到五大新发展理念首位***[13]**。**自《国民经济和社会发展第十三个五年规划》明确“创新是引领发展的第一动力”以来，中国正在积极优化宏观创新环境，并逐步向创新驱动型经济发展转型，开辟了一条可持续发展之路。中国已进入“模仿创新、商业创新、科技创新”曲线中最陡峭的一段，攻克科技创新难题将为未来经济发展带来无限可能。

### 3.1 生物医药创新对提升人民健康至关重要。

***过去十年，伴随着医药卫生体制改革的有序推进，中国在医疗保障、公共卫生服务、医疗服务、药品供应保障四大体系均取得了瞩目成就。***如今，中国已成为全球第二大药品消费市场。尽管如此，医药工业的高速增长仍不能高质量地满足日益增长的健康需求，恶性肿瘤等重大疾病严重威胁中

[13] 五大新发展理念：创新、协调、绿色、开放、共享。

国人民的卫生健康，亟需创新的解决方案。研究表明，面对当前无法治愈的疾病，突破性创新至关重要，可显著降低疾病负担。此外，此次全球疫情也凸显医药创新在疫情防控、经济恢复中的重要性，愈加明确生物科技创新产业对健康中国的战略意义。因此，生物医药产业需要重点发展针对重大疾病预防和治疗的新技术、新方案和新产品，以早日实现健康中国行动中癌症防治目标。

***中国也早已将生物产业纳入顶层发展战略，表明生物科技产业创新是现阶段及未来中国重点关注及发展的方向。***《“十三五”生物产业发展规划》明确生物产业是中国战略性新兴产业的主攻方向，加快壮大产业动能，对建设健康中国具有重要意义。2015 年 5 月，国务院出台《中国制造 2025》，将生物医药列入突破发展的重点领域。2016 年 10 月，中共中央、国务院印发《“健康中国 2030”规划纲要》，鼓励完善产学研用协同创新体系，大力发展医药创新和转型升级。

创新药企将作为医药产业发展的主要推动方，推进与国内企业深度合作，利用大数据、人工智能、5G 等技术手段实现医药研发、临床诊疗、健

康管理等全流程理念和技术革新，在“以治病为中心”向“以人民健康为中心”转型中扮演中坚力量。

### 3.2 当前中国政策环境仍存在完善空间，以促进生物医药产业创新可持续发展

***近年来，中国在支持临床研究、加强监管审批、提高支付保障能力等方面取得了长足进步，政策环境的显著改善，推动了医药创新。***对临床试验机构备案制资格认定实行管理，临床试验中心数量由 2015 年的 375 家增长到 2019 年的 1072 家[14]。2018 年公布的临床试验 60 天默许制显著提升了临床试验效率。2020 年发布新修订的《药品注册管理办法》，明确规定优先审评审批、突破性治疗审批、附条件审批、特别审批等快速审评程序，4 个新冠疫苗通过附条件审批上市。而先行在 2016 年出台的优先审评审批政策，使加快审批上市药品由 2016 年的 7 个增长到 2019 年的 82 个品种[15]。此外，医保药品目录更新频次不断提高，2020 年确定每年动态调整机制，创

[14] 中国医药创新促进会 ，中国外商投资企业协会药品研制和开发行业委员会. 《构建中国医药创新生态系统 系列报告第一篇：2015-2020 年发展回顾及未来展望》[R/OL].(2021-03-02) [2021-03-02] http://cnadmin.rdpac.org/upload/upload_file/1614646546.pdf

[15] 药品审评中心. 《2019 年度药品审评报告》[R/OL].(2020-07-30) [2021-03-03] http://www.cde.org.cn/news.do?method=largeInfo&id=68f4ec5a567a9c9a

新药从上市到通过谈判纳入医保目录的时间大幅缩短，从 2017 年的 7.8 年降到 3.7 年，更有 14 个药品于上市当年进入医保。一系列政策改革“组合拳”，加速了药品上市和准入，显著提高了药品可及性。

***尽管医药创新政策领域取得了诸多成就，仍有一些关键方面有待提升。***例如，***一方面可以通过资助创新药、救命药研发，以满足患者日益增长且尚未满足的需求。***近十年来，中国癌症五年生存率从 30.9%上升到 40.5%，但与发达国家相比仍有较大差距[16]。其中关键原因之一是临床疗效更佳的创新药虽已在中国上市，囿于支付、进院等因素仅可惠及部分患者。截止目前，2016-2020 年获批的创新药仍有一半未进入医保目录。***另一方面，国家医保准入机制有待进一步考虑创新药品多样性的价值。***考虑到创新药研发周期长、投入大、风险高，建议医保准入谈判在降低药品价格、提高患者可及的同时，综合考虑医药企业长期创新积极性，探索支持医药产业可持续发展的卫生政策，给予创新医药产业合理回报，例如探索风险共担的创新支付模式，保证药企持续研发投入，促进生物医药创新产业蓬勃发展。

[16] 中国政府网. 《中国居民营养与慢性病状况报告（2020 年）》[R/OL].(2020-12-23) [2021-03-03] http://www.gov.cn/xinwen/2020-12/24/content_5572983.htm

### 3.3 政策建议

***首先，生物医药产业创新发展离不开鼓励创新的政策生态环境。***创新药物、器械等产品开发需要时间、知识、技术积累，加强知识产权保护，营造崇尚创新的社会氛围，可释放医药产业创新活力，促进产业不断创新、发展。此外，建立长期稳定的政策体系，持续完善药品评审制度、监管制度逐步与国际接轨，也是推动医药产业深化发展的关键。

***其次，完善的支付政策可有效驱动供给侧发展和创新。***以医保支付为例，建立基于价值的、科学综合的药品临床价值评定体系，将更多创新药纳入医保目录，提高生物医药产业发展的可持续性。同时，参考国际经验，探索注入风险共担的创新支付方式，以应对创新药物在医保准入过程中存在的预算影响或疗效不确定的挑战。合理健全的医保支付政策环境将支持生物技术公司积极建设以科学为主导、以满足患者需求为驱动的生物医药产业。

### 3.4 罗氏贡献

***自进入中国 90 多年以来，罗氏一直践行支持中国生物医药产业创新全面发展的理念。***2019 年 9 月，罗氏中国研发中心落户上海，标志着罗氏继续深度参与中国生物医药产业的发展。该中心通过与研发机构、本土企业和研究型医院开展深入合作和人才交流，推动中国生物医药产业创新研发能力的整体发展。未来，罗氏愿同中国政府加深交流与合作，携手推进健康中国生物医药创新发展，持续引入突破性技术扎根中国，推动中国整体研发能力的提升，助力中国早日跻身全球医药创新研发第一梯队。

## 四、结论：医疗健康数据和生物医药产业创新的前瞻性应用，助力健康中国，推动中国成为全球创新领袖

在助力健康中国的过程中，罗氏集团非常荣幸可以持续分享在诊断、生物制药、行业洞察等领域的一体化解决方案。展望未来，罗氏集团将继续作为中国政府的差异化合作伙伴，持续践行“以患者为中心”的价值观，满足中国患者多样化需求，提供更高质量的产品及突破性的解决方案。同时，罗氏集团也将持续着眼医疗健康生态，不断造福患者、减轻国家疾病负担，最终助力实现“健康中国”战略目标。

# Accelerating Innovation in Healthcare Transformation to Explore Healthy China Opportunities

*By Dr. Severin Schwan, CEO, Roche Group*

***Abstract***

Following a period of continuous social and economic development in China, the central government has elevated the people's health as a key priority in the country's ongoing strategic development. The government-proposed *Healthy China Initiative* promotes a shift in the current healthcare management framework from treatment-focused to prevention-focused. To support the *Healthy China Initiative* and also to contribute to high- quality economic development two opportunities will play critical roles:

(1) Advancing responsible healthcare data use

Strategic use of meaningful data at scale (MDAS) and advanced digital healthcare technologies can accelerate transformation in the approach toward (a) managing major, complex diseases, such as malignant tumors; (b) achieving early-screening, -diagnosis, and –treatment; and (c) encouraging a paradigm shift in utilization of health care resources. China's global leadership in digital

transformation provides a unique and differentiated platform to model improvement in the quality and efficiency of healthcare service delivery through a deeper integration of healthcare and advanced digital technology, such as big data and artificial intelligence (AI).

Against the backdrop of fast-evolving, rapidly-developing digital technology, countries globally have begun to realise data's potential in addressing complex, intractable healthcare problems; hence also benefiting from responsible use of data as a production factor in healthcare industry growth. The COVID-19 pandemic further demonstrates the role of big data in the healthcare domain, such as its importance in proactively preventing and swiftly treating COVID-19 cases. On this front, the Chinese government has issued a series of regulations and policies to promote the application of healthcare data and unlocking its potential value, while still evaluating issues such as data ownership, quality, and safety. To further enhance these efforts and unlock full value for health system stakeholders, the following policies and actions may be considered:

- Establishing an integrated patient-centric healthcare database
- Building a dynamically-adjusted, classified data management mechanism to ensure legitimate use
- Fully maximizing the potential of digital technology and healthcare data through incentivizing development of innovative use case scenarios

- Improving healthcare stakeholder awareness of a "patient-centric, data-driven" healthcare system, while strengthening patient participation

(2) Encouraging biomedical innovation

Biomedical innovation is crucial to improving individuals' health, particularly in the treatment of complex diseases with high unmet need. In recent years, China has successfully promoted the development of the biomedical industry, and there is additional value creation opportunity through continuing to foster an environment that recognizes and encourages innovation as a strategic priority.

Specifically, China has made considerable progress in supporting clinical research, tightening supervision and approval, and improving healthcare security capabilities, ultimately promoting biomedical innovation. To continue on this positive trajectory and extract the full impact these efforts have had, ensuring sustainable financing and patient access to produced innovation will continue to encourage and incentivize both domestic and global ingenuity and investment. The required high investment and long investment cycles inherently come with significant risks of failure. Having the appropriate reward mechanisms and incentives in place is necessary to continue to encourage both longstanding and especially nascent players. The combination of empowered policies along with free market-driven dynamics will lead to more breakthrough therapies for Chinese

patients and an environment that supports broad, affordable access. China is well-positioned to foster an environment of this nature with the broad reach of its long established universal health coverage for its population and the empowerment of government-issued policies. Key areas for potential consideration as part of the ongoing investment in biomedical innovation and to support sustainable healthcare financing for patients' needs may include:

- Continuing to foster a policy-empowered, market-driven environment with policies that highlight value recognition around innovation and reward innovative value creation – e.g. enhancing the review and listing mechanism in the national healthcare security system
- Enhancing medical insurance reimbursement policies and align total medicine innovation value with health system priorities through policies that actively explore and encourage innovative healthcare financing models – e.g. innovative risk-sharing payment models

As a leader in digital and personalized healthcare and a global healthcare company that operates in 100+ countries worldwide, Roche has accumulated rich industry experiences in the global healthcare market across the value chain. Roche is well-positioned to create new development opportunities brought to China by healthcare data and the innovation-driven biomedical industry and is eager to

contribute its breadth of experiences, from R&D to market access innovation to insights capabilities. With a 90+ year history in China Roche continues its commitment to being a differentiated partner. This includes leveraging integrated, end-to-end capabilities across its full range of businesses and investments, as exemplified by recent commitments to build a next generation R&D engine in China to meet the needs of patients in China and worldwide.

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## Chapter 1, Introduction: Strategically focusing on the application of healthcare data and biomedical innovation as opportunities to build a Healthy China together

***China's economy and society have realised leapfrog development and made remarkable achievements in the past 40+ years of reform.*** Over this period, China has hit key economic and social milestones, including laudable accomplishments in eliminating absolute poverty and operating as the world's sole major economic growth engine. China's position of having the world's second-highest total

investment in research and development (R&D) not only demonstrates the coordination and sustainability of its economic development as a country but also is a key indicator of the country's transformation into an innovation-driven economy.

***China's prioritisation of the people's health for strategic development*** in the Fifth Plenary Session of the 18th Communist Party of China (CPC) Central Committee and the October 2016 issuance of the *Healthy China 2030 Planning Outline* demonstrate China's commitment to the construction of "Healthy China" and clearly highlight the importance of health as a prerequisite for the country's all-around development. Additionally, *The Outline*, stresses enhancing disease prevention efforts and a desire to accelerate the transformation of healthcare management increasingly from "treatment-centric" to "health-centric."

***Healthcare data application and biomedical innovation are two critical areas that will bring new opportunities for the development of China's rapidly growing healthcare industry.*** The continuous advancement of digital technology will accelerate the rapid development of the healthcare industry and further propel China towards its vision as a powerhouse biomedical innovator. Focusing on the intersection of healthcare data applications and biomedical innovation will bring a

unique competitive advantage to China and accelerate its entry into the first echelon of global biomedical industry innovation. Digitization will help China meet the multi-faceted, diversified, and personalised health needs of individuals more accurately, while comprehensively promoting and advancing *Healthy China 2030*.

***Roche welcomes the opportunity to support China in achieving strategic goals set forth in Healthy China 2030 through relevant experiences and technologies in the field of healthcare.*** Since its establishment in Switzerland in 1896, Roche has been a pioneer in healthcare disruption and breakthroughs. Roche Group biopharmaceuticals and diagnostics protect patients' health in several key areas, including oncology, infectious diseases, antivirals, transplants, and rheumatism. In 2020, Roche Group ranked the largest biotech company in the world, investing over USD 13 billion into R&D, more than any other healthcare company in the world. With the unique advantages stemming from industry-leading pharmaceutical/biotechnology and diagnostic businesses coupled with key acquisitions of next-generation genomic sequencing and insights businesses, Roche Group has also become a leader in personalised healthcare.

Roche has had a front seat in witnessing China's impressive development over the decades and as an early partner was the first to develop a full pharmaceutical value chain in China and, going forward, Roche remains to partnering to support

China in its drive toward its next chapter of innovation-led development. Following the vision outlined in the *Healthy China Initiative,* Roche has actively participated in advocacy and the practice of disease prevention and treatment. Recently, under the guidance of the Healthy China Action Promotion Committee's Office, People's Daily hosted a "Healthy Chinese People" round-table forum during the Two Sessions in 2021. Roche advocated that all societal sectors should work together to pay attention to cancer prevention and treatment, and build a closed-loop ecosystem of tumor screening, diagnosis, and treatment.

## Chapter 2: Healthcare data applications will uncover new opportunities for establishing a *Healthy China*

With the rapid development of information technology, countries globally have realised the strategic role of data as a production factor in the growth of the healthcare industry. ***The organic integration of the deepening digitalisation and healthcare will promote the rapid development of digital healthcare.*** A *McKinsey r*eport *(Big Data Revolution in US Health Care)* predicted that digitalisation in healthcare will lead to a 12 to 17 per cent reduction in health expenditure. With big data deeply integrated into all facets of the healthcare system, its scaled-up system-wide impact will be reflected across all aspects of healthcare, from pharmaceutical

R&D to clinical treatment and health management, and will significantly improve the efficiency of the healthcare system.

***In the post-epidemic era, accelerating the release of data elements' value has become a global development trend.*** In 2020, COVID-19 exposed a series of shortfalls in many countries' and cities' social governance capabilities and public health systems. Big data has played a crucial role in the healthcare industry as a counteragent. Roche has been a pioneer of harnessing digital solutions and insights in improving the efficiency and delivery of healthcare across the value chain and has launched cooperative applications in many countries. For example, during the pandemic, Roche collaborated with companies in Canada and other countries to launch a data science coalition and establish a publicly available population database. This partnership leveraged Roche Group's advanced diagnostic data solutions to contribute to epidemic prevention efforts**.** This experience has continued to build on Roche's industry-leading platform around meaningful data at scale (MDAS), digitization, and appropriate use cases for value creation in the healthcare industry. In full cooperation with and following the lead of China's government, Roche is fully committed to proactively exploring additional opportunities that data applications and technologies can bring to support the realisation of a *Healthy China*.

**2.1 Internationally, countries have begun to actively explore initiatives in the area of digital medicine**

Denmark and its Ministry of Science, Innovation and Higher Education have jointly established a national biobank, collecting more than 10 million bio-samples across various diagnostic categories. In addition, the ***national biobank is connected to a significant number of civil registries that contain the population's electronic medical records (EMRs***), assisting researchers in accessing comprehensive healthcare data, such as patient prognoses, rehabilitation and health management data. The biobank not only facilitates innovation of the country's healthcare industry, but also supports disease prevention, treatment, and progression-tracking during clinical practice.

In England, the Ministry of Health initiated the ***'100,000 Genomes Project' to collect and sequence 100,000 genomes from cancer and rare disease patients, while also collecting clinical and childhood illness data from patients' medical records.*** Since 2017, the project has gradually optimised the research environment, through enrichment and improvement in accuracy of genomics data, yielding a year over year increase in the number of academic papers published in the fields of

cancer and rare diseases. In addition, the research results of the project have also been applied to the training of local healthcare staff to help them better understand the needs of patients and improve the quality of healthcare services.[17]

### 2.2 In recent years, China has made progress in the application of healthcare data

The central government has issued a series of regulations and policies to encourage the application of data. In 2016, the State Council issued *Opinions on Promoting and Standardizing Big Data Application in the Healthcare Industry*, integrating big data and healthcare development and raising the concept to become a national strategy. Following this, the National Health Commission released the *National Population Health Informatization Development Plan of the 13th Five-Year Plan (FYP)* and other policies to vigorously promote the exploration and construction of healthcare informatization and healthcare big-data service system by consolidating infrastructure, deepening data application and developing innovative models, etc. In April 2020, the central government's *Opinions on Accelerating the Building of a Better Institutional Mechanism for the Market Allocation of Production Elements* clearly defined the strategic position of data by

[17] Genomics England. (2020). Delivering the Project. [2021-03-02] https://www.genomicsengland.co.uk/about-genomics-england/the-100000-genomes-project/

designating it as a new type of production factor for the first time. In addition, the government aimed to "promote the improvement of data classifications and hierarchical security systems within the big data ecosystem." Later in May, the State Council proposed to "establish a management mechanism of data resource list, and improve standards and measures for data ownership, data sharing, and data transactions."

***At present, China has established several digital platforms with grading, classification, and different applications*** to provide preliminary healthcare information and data-sharing for businesses, scientific research, and other services, which played an active role during the epidemic. In June 2019, *China established the National Genomics Science Data Center (NGSDC), creating a shared management platform dedicated to the R&D of biodiversity and health big data.* During the epidemic, the data centre's COVID-19 information database collected and released 56,036 pieces information of COVID-19 viral sequences and 208 pieces of relevant clinical information.

**2.3 There is an opportunity to further improve and develop the application of healthcare data.**

***Although China has made many achievements in healthcare digitalisation, its continuing development still faces many challenges.*** To share and use meaningful data at scale (MDAS), which contains medical value, it needs to address questions related to data ownership, quality, security, as well as means to harness its potential healthcare value (see 2.3.1-2.3.3) . These problems are worth joint exploration and resolution through government and industry partnership.

### 2.3.1 Data ownership

***As a new type of production factor, data—like land, capital, labour, and other production factors—involves ownership issues.*** In theory, there is no uniform, complete and general definition of data ownership, nor is it entirely recognised and clearly defined in law. Establishing an integrated healthcare database and clarifying data ownership is a fundamental task. Only when the rights and interests of data owners and relevant stakeholders are fully protected can efficient data circulation occur and increased data accessibility be fully achieved.

***Some places in China have begun to test different approaches to managing meaningful data at scale (MDAS) and data ownership.*** In 2019, Shanghai pioneered the release of *Shanghai's Interim Measures on Open Public Data,* which

defines the scope of public data as data collected and generated by public management and service agencies in the process of performing their duties. Simultaneously, individuals *(i.e. natural persons, legal persons, and unincorporated organizations)* are allowed to submit evidence and suspend the opening of public data that may infringe on individual privacy. Shenzhen recently released a public data policy—*Shenzhen Special Economic Zone Data Regulations (Draft for Comment)*—clearly defining public data as state-owned assets and indicating that healthcare data collected by public healthcare institutions will be established as state-owned assets. Nevertheless, under this policy, individuals still have the right to understand what data is being collected and to provide consent during data collection. Additionally, the Shenzhen Municipal Health Commission is setting up a healthcare big data scientific research and sharing platform, whose data access and usage rights may be open to institutions and individuals in the future.[18]

### 2.3.2 Data quality

[18] China Government Procurement Platform. (2019). *Shenzhen Medical Information Center's Announcement on Shenzhen Healthcare Big Data Research and Sharing Platform (Phase I) Bidding Result.* [2021-03-04]. http://www.ccgp.gov.cn/cggg/dfgg/zbgg/201909/t20190911_12880660.htm

While healthcare data is abundant and complex, only when it reaches a high level of quality, matched with rigorous data analysis methodologies, can it support medicine development, standardized supervision, and clinical treatment.

***Currently within the healthcare industry, data quality is a major concern.*** Different analytical purposes and data users—e.g. researcher and supervisors—have diverse demands of data quality (e.g., clinical relevance, accuracy, completeness, transparency, and scalability). In general, the quality of most real-world data (RWD) currently cannot meet the requirements of data users. Among them, the problem of insufficient longitudinal RWD is particularly prominent. In traditional databases, health data usually exists in the form of scattered, fragmented or incoherent data points. Longitudinal data is of high value and can provide insights on evaluating clinical pathway designs, supporting medicine optimizations, and disease management, as well as providing strong support to analyze the impact of clinical decisions on efficacy.

### 2.3.3 Data security and unlocking the potential value of data

Under the trend of digitalisation, privacy issues have increasingly become a social focus, with many countries introducing policies and measures to try and meet

this challenge. For example, the EU issued the *General Data Protection Regulation (GDPR)* in 2018, emphasising the principle of informed consent to protect personal information. The freedom to operate with respect to storage, processing, or release of personal data must be obtained through the data subject's informed consent. If the subject submits a legal informed consent withdrawal application, the data user must process it promptly. Similarly, the Australian government has issued the *Guiding Framework for the Secondary Use of My Health Record (MHR) System Data*, requiring the establishment of a Data Governance Board to review data applicants, ultimately helping to protect patient data privacy.

***At present, China has also begun to gradually improve the management regulations concerning healthcare data security.*** In 2019, the State Council issued the *Data Security Management Approach (Draft for Comment),* formulating a framework of regulations that guide the collection, storage, transmission, processing, and use of data, as well as measures around data security protection, supervision, and management. In addition, the *Guidelines for Information Security Technology, Health and Medical Information Security* ("*Guidelines*"), which specifically encompasses healthcare data, was also being formulated. The *Guidelines* put forward detailed recommendations on security measures for typical healthcare data use scenarios and corresponding management processes to

providing detailed guidance for actual operations. Building on the existing foundation and principles in China, the Chinese government can also refer to relevant international experiences to further explore formulation of a comprehensive and complete healthcare data management system.

### 2.4 Policy Recommendations

#### 2.4.1 Optimize top-level design while establishing an integrated patient-centric healthcare database

Breaking through database barriers from different fields, integrating multiple resources, and improving the operational efficiency of the entire healthcare system with high-quality data is the key to further unlocking the potential value of meaningful data at scale (MDAS). The central government can encourage local areas to conduct pilot projects, explore the opening-up of various healthcare data resources, link electronic medical records, genomic data, biological samples, health management files, as well as introduce innovative data sources, such as wearable devices into the database. All these facets can help to establish an integrated patient-centric healthcare database that leverages high-quality data to improve the operational efficiency of the whole healthcare system and save social costs.

### 2.4.2 Establish a dynamically-adjusted, differentiated data management mechanism

***Considering the sensitivity of health data, the centralised storage and management of enormous amounts of data pose significant challenges to data management capabilities.*** Therefore, in order to protect and ensure legitimate use, after the establishment of an integrated healthcare database, pilot areas can consider exploring a management mechanism for differentiated data classifications. By adopting a data management mechanism, local and central governments can more effectively control and supervise different subjects' rights to access data, reducing the risk of illegal access or data misuse. Based on this, the differentiated data management mechanism can also be integrated into emergency public health responses, releasing relevant epidemic-related medical data promptly to aid in vaccine and medicine R&D, conducting epidemiological investigations, and implementing relevant quarantine solutions.

***Relying on a hierarchical differentiated data management mechanism, local and central governments can explore relaxing access to various data types for different industries.*** This mechanism could encourage related industries, such as

the biomedical industry, to leverage their advantages to ensuring legitimate use of data, and to further explore new areas for integrating industries.

### 2.4.3 Encourage partnerships and cooperative efforts to fully maximise the potential of information technology, medical data, and innovative data scenarios

To achieve goals pertaining to high-quality data collection and management, it is also necessary for multiple parties to collaborate and make full use of information technology to achieve in-depth data analysis.

***To better meet the personalised health needs of patients, Roche recommends leveraging new technologies and meaningful data at scale (MDAS) to carry out precise oncology medicine research and development.*** The development of modern biomedical technology—especially in the field of complex diseases such as tumours and rare diseases—is rarely achieved independently by one institution. Different research fields, companies, and industries should collaborate and innovate together to promote the improvement of technology. The Chinese government could consider actively encouraging organizations from diverse industries to

explore innovative partnerships for data-sharing, to work collaboratively, and develop advanced treatment solutions that can meet patients' needs.

***Medical institutions can be encouraged to apply advanced information analysis technology, promote the development of clinical decision support systems (CDSSs), improve the level and quality of diagnosis and treatment, and optimize patient experiences.*** Through innovative information technology, massive amounts of clinical data can be transformed into information that guides actual operations and provides clinical decision support for medical staff. CDSS can support doctors in transcending the limitations of their own experience and knowledge, and to utilize a large number of research results and past practical experience to design the best diagnosis and treatment plan for patients.

### 2.4.4 Improve medical staff's awareness of a "patient-centric, data-driven" healthcare system, while strengthening patient participation

***Medical staff are the main force behind medical services, and patients are at the center of the healthcare system.*** It is very important to encourage both parties to actively participate in building a "patient-centric" ecosystem. The Chinese government can test a variety of measures to promote collaboration between doctors

and patients and jointly promote the advancement of the healthcare system. For example, efforts could be taken to deepen medical staff's understanding of "patient-centric," promoting and popularizing this concept. Similarly, patients could be encouraged to participate in all aspects of digital healthcare, helping patients to realize patient empowerment, and enabling them to truly benefit from digital medicine.

### 2.5 Roche's Contribution

***Roche has global, industry-leading experience in the management, integration and analysis of large volumes of medical data, which can help China further realize its healthy China strategy***

***Roche has created the world's first clinical genome database of cancer patients.*** Roche's subsidiaries Foundation Medicine Inc. (FMI) and Flatiron Health jointly created the world's first database that integrates oncology patients' genomic data and clinical data. The database contains not only clinical data—such as demographic data, medication, diagnosis, tumor metastasis date, medication history, medical examination results—but also genomic data, such as tumor genomic analyses, genomic changes, samples, and biomarkers. The database has large

volumes of high-quality data, which has the potential to assist in more efficient clinical decision-making and to accelerate the realization of personalized healthcare.

***Roche is actively involved in personalized cancer care in China.*** In April 2018, Roche's FMI subsidiary signed a cooperative agreement with China's DIAN Diagnostics, and subsequently launched FoundationOneCDx (F1CDx), the first comprehensive genomic-sequencing analysis service on the market for solid tumor patients. The genomic analysis presented by the F1CDx test can provide doctors with comprehensive molecular information, helping to guide doctors in formulating targeted cancer treatment and prevention plans. F1CDx for solid tumors will break the traditional tumor diagnosis and treatment model and establish a new standard for personalized patient care in China. Furthermore, following the wide-spread use and application of this technology, it is expected that more tumor data in China will provide even more effective support for future cancer prevention, diagnoses, and treatments.

Continuing on its legacy of commitment in China, Roche has had the privilege of participating in the *Healthy China Initiative*, to transparently share Roche's global experience and leading biotechnology solutions in promoting early cancer

screening, diagnosis, and treatment, and to support China in achieving its *Healthy China* ambitions.

## Chapter 3: Innovative biomedical industry development will generate new opportunities for establishing a *Healthy China*

***At the Fifth Plenary Session of the 18th CPC Central Committee, President Xi Jinping prioritised 'Innovation' at the top of five new development concepts.***[19] As the *13th Five-Year Plan for National Economic and Social Development* clearly stated "innovation is the first driving force for development," China is currently actively optimising the macro-environment for innovation and gradually transforming into an innovation-driven economic development model, creating a path for sustainable development. China has entered the steepest section of the curve of "imitative innovation, business innovation, and technological innovation". Overcoming difficulties with regards to technological innovation will bring significant possibilities for China's next stage of economic development.

### 3.1 Biomedical innovation is essential to improving people's health

[19] Five new development concepts: Innovation, Harmony, Green, Open, Sharing.

During the past ten years, with the continuous advancement of China's healthcare system reform, China has made remarkable achievements in four aspects: healthcare security,public health services, healthcare services, and medicine supply reliability. In fact, China has become the world's second-largest consumer market for medicines. However, despite rapid growth, traditional pharmaceutical industry faces limitations in fully meeting the population's increasing healthcare demands. For example, major diseases such as malignant tumours seriously threaten the Chinese people's health. Studies have shown that in the face of currently incurable diseases, breakthrough innovations are essential to reducing disease burden significantly. Also, during the COVID-19 pandemic, the importance of health-related technological innovation has become even more prominent in epidemic prevention and control efforts, as well as the economy's recovery. In other words, the strategic significance of an innovative biomedical industry to accomplishing a *Healthy China* has become increasingly evident. It plays a critical role through the development of new technologies, programs, and products.

***China has included the biomedical industry in its top-level development strategy.*** The *13th Five-Year Plan for the Development of Biological Industry* clarified that the bio-industry is a core part of China's strategic, emerging industries. In May 2015, the State Council issued *Made in China 2025*, identifying

biomedicine as a key area for breakthrough development. In October 2016, the CPC Central Committee and the State Council jointly issued the *Outline of the Healthy China 2030 Plan*, encouraging improvement of the "industry-university-research-application" collaborative innovation system, biomedical innovation, as well as the industry's transformation and upgrade.

Innovative biotechnology companies are currently collaborating with domestic partners to leverage big data, artificial intelligence, 5G, and other technological advancements to promote the innovative development of the biomedical industry. Biotechnology companies also play a crucial role in promoting healthcare transformation from "treatment-centric" to "health-centric" models.

### 3.2 There is an opportunity to evolve China's policy environment to promote innovation and sustainable development of the biomedical industry

***In recent years, China has made considerable progress in supporting clinical research, tightening supervision and approval, and improving healthcare security capabilities—with the policy environment significantly improving and health technology innovation being promoted.*** China has implemented a record system to manage the accreditation of clinical trial institutions. The number of

clinical trial centres has increased from 375 in 2015 to 1,072 in 2019.[20] In 2018, the 60-day approval system for clinical trials was announced, significantly improving clinical trial efficiency. The newly revised *Medicine Registration Regulations* was issued in 2020, introducing several expedited review processes, such as priority review and approval, review and approval of breakthrough medicines, and conditional and special medicine approval. Four COVID-19 vaccines have been approved through conditional approval procedures. The priority review and approval policy introduced in 2016 increased the number of fast-approved medicines from 7 in 2016 to 82 varieties in 2019.[21] Additionally, the frequency of updating the *National Reimbursement Drug List (NRDL)* has continually increased, with an annual dynamic adjustment mechanism being established in 2020. The duration in years for innovative medicine inclusion on the NRDL through negotiation has been greatly reduced to 3.7 years, from an average of 7.8 years in 2017. Fourteen medicines entered the NRDL in the same year they were approved. These collective policies, among others, have driven important reform in medicine approval procedure and broader medicine access, greatly accelerating market access reimbursement and significantly improving patient medicine accessibility.

[20] China Pharmaceutical Innovation and Research Development Association & R&D-based Pharmaceutical Association Committee of China Association of Enterprises with Foreign Investment. (2021). *the first part of the series of reports on the construction of China's pharmaceutical innovation ecosystem: 2015-2020 development review and future prospects*. [2021-03-02] http://cnadmin.rdpac.org/upload/upload_file/1614646546.pdf

[21] Center for Medicine Evaluation. (2020). *2019 Medicine Evaluation Report*. [2021-03-03] http://www.cde.org.cn/news.do?method=largeInfo&id=68f4ec5a567a9c9a

***Nevertheless, there are still key aspects that may be reviewed.*** These include two considerations:

***(1) Supporting overall access through financing of innovative, life-saving and life-enhancing medicines to meet patients' growing and unmet needs.*** While China has made significant strides in the last decade in improving the five-year cancer survival rate from 30.9 per cent to 40.5 per cent, this survival rate still lags that of developed countries.[22] One key reason is that despite innovative medicines with better clinical efficacy having approvals for the Chinese market, they may only benefit a limited number of patients due to factors such as lack of national reimbursement and public hospital formulary listing. In fact, half of the innovative medicines approved during 2016 to 2020 have not yet entered the NRDL. ***(2) Strenghtening* access mechanism to *China's national healthcare security by accounting more for diversity of innovation.*** Considering the long R&D cycle, large investments, and high risks associated with developing innovative medicines, it is suggested that apart from reducing medicine prices and increasing accessibility, national medical insurance negotiations could explore approaches that comprehensively consider protecting biotechnology companies' enthusiasm for innovation. This may include policies that support sustainable health system

[22] State Council. (2020). *Report on Nutrition and Chronic Disease Status of Chinese Residents (2020)*. [2021-03-03] http://www.gov.cn/xinwen/2020-12/24/content_5572983.htm

medicine financing, while ensuring reasonable returns to the innovative biomedical industry. One example may be to encourage and reward creative reimbursement models, such as risk-sharing agreements..

### 3.3 Policy Recommendations

***First, innovative biomedical industry development requires a policy environment that protects innovation.*** R&D for innovative medicines, medical devices, and other products requires time, knowledge, and the accumulation of technology. Strengthening intellectual property rights protection, improving the legal system, encouraging the protection of innovative achievements, and creating a social atmosphere that advocates for innovation can all contribute to the biomedical industry's innovative vitality and promote the industry's development. Additionally, establishing a long-term, stable policy system, continuous improvement of the review system of health technologies, and gradual integration of the regulatory system with international standards are also keys to promoting the biomedical industry's sustainable development.

***Second, a sound healthcare financing policy that rewards innovation is required.*** For example, regarding national basic medical insurance (BMI) coverage, the establishment of a value-based, scientific and comprehensive health technology assessment, evaluation, and appraisal system and inclusion of more innovative

medicines onto the NRDL can enhance the sustainability of the biomedical industry's development. Additionally, China could refer to international examples and establish innovative risk-sharing payment mechanisms in order to deal with potential uncertainties including budgetary concerns with respect to the increased availability of newly approved innovative medicines in the NRDL. A sound and appropriate healthcare financing policy will support biotechnology companies in their enthusiasm in building towards a biomedical industry that is led by science and driven by unmet patient-needs.

### 3.4 Roche's Contribution

***Since entering China's market 90+ years ago, Roche has supported China's biotechnology industry's overall development.*** As a signal of its continued commitment to the biomedical industry's next stage of development, in September 2019, the Roche Innovation Center was established in Shanghai (RICS). The centre aims to promote the overall development of China's innovative biotechnology industry's R&D capabilities through in-depth cooperation and talent exchange with local institutions, companies, and research hospitals. Roche is committed to working with the Chinese government to promote innovation and development of the country's biotechnology industry, continuing to introduce cutting-edge

technologies into China, further building out China's R&D capabilities, and supporting China in becoming a top-tier global leader of biomedical innovation.

## Chapter 4, Conclusion: Forward-looking application of healthcare data and biomedical innovation to enable achievement of *Healthy China* and propel China to global innovation leadership

In support of the *Healthy China* goals, Roche is privileged to build on its position in China via its existing suite of solutions across diagnostics, biopharmaceuticals, and insights capabilities. In going forward, Roche aspires to differentiate itself in the eyes of China's health system and leaders as a partner that has a deep commitment to practicing patient-centric values, fulfilling diverse Chinese patient needs, and providing China with high-quality products and breakthrough solutions. In its approach, Roche will continue as a partner to focus on the overall healthcare ecosystem and explore holistic, shared value opportunities in reducing disease burden.