

Supporting Clinical Trials Operations

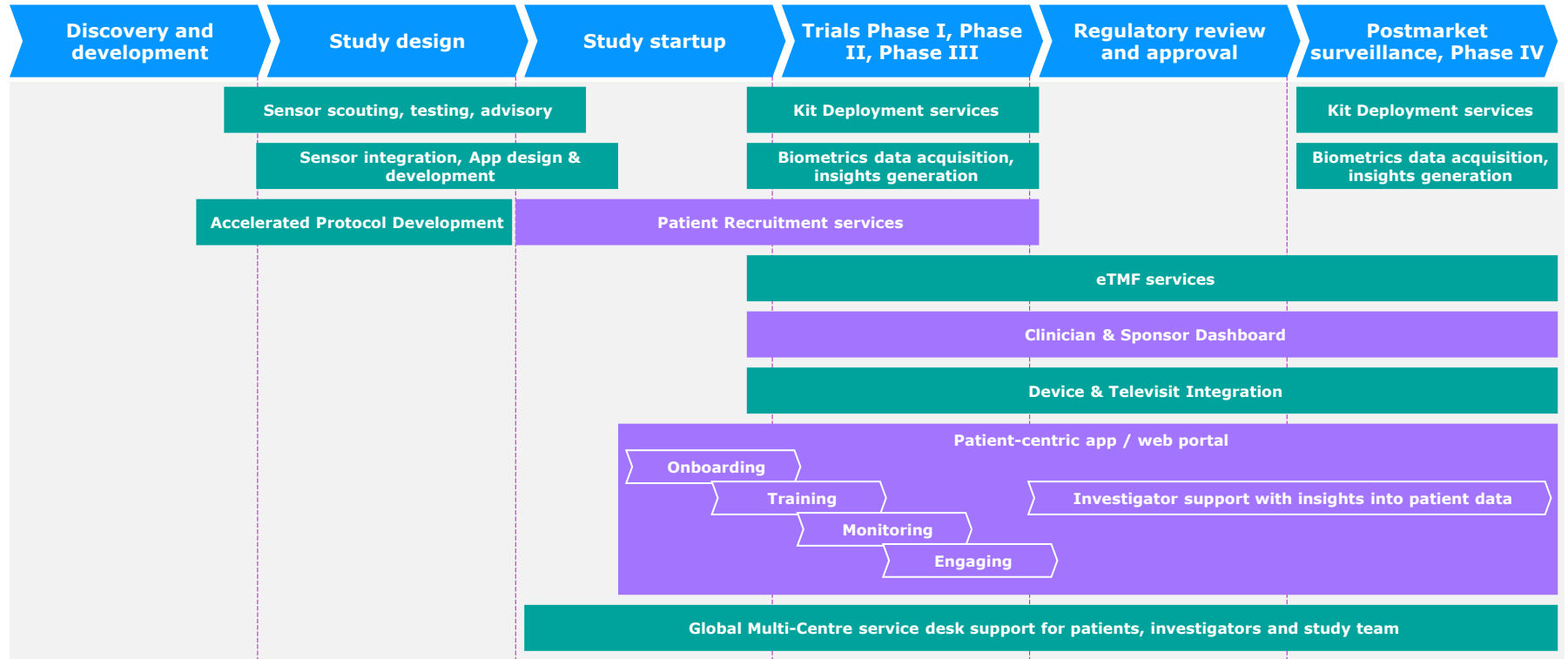


Agenda

- 01. Atos' coverage of the Clinical Trial Process
- 02. Patient recruitment through alternative channels
- 03. Sensor Advisory, Integration & Insights generation to support Digital Biomarkers
- 04. Operationalization of decentralized studies including hotline support
- 05. Management of clinical & ancillary supplies
- 06. Digital Twin to simulate patient condition

Atos' coverage of the Clinical Trial Process...

the most critical part of Drug Research & Development, and early Commercialization



■ Solutions and services delivered by Atos

■ Solutions and services delivered by Atos with partners' involvement

Experienced benefits of Atos' services spread among different areas ...

... with measurable evidence of value delivery (already proven by project experience)

Value delivery evidence



Fast study operationalization: Faster **study planning** and operationalization, **patients' identification, selection, onboarding** to speed up **recruitment**

- **1-2 weeks** from support **request to proposal**
- **2-3 weeks** from contract **signature to study operationalization**
- **Recruiting in 6 weeks vs. 5-6 months** originally forecasted
- **Support hotline** for patients, investigators and study team



Flexibility to adapt: **Change** on short notice to **adapt on study's requirements**

- ***New site activated** in 2-3 days
- ***New patient cohort** included within 5-7 days



Safe use of technologies: **Securely use** of whatever **technologies, Apps, sensors, and appliances** with **high-quality data**, delivered **on time**

- E2E **sensor scouting, evaluation, testing**, lifecycle management
- **30%** faster Sensor-to-Study deployment
- **GDPR, compliant** comprehensive digital phenotyping
- Targeted **insights generation**
- **5 stars** rating patient-centric Apps with fully decentralized experience

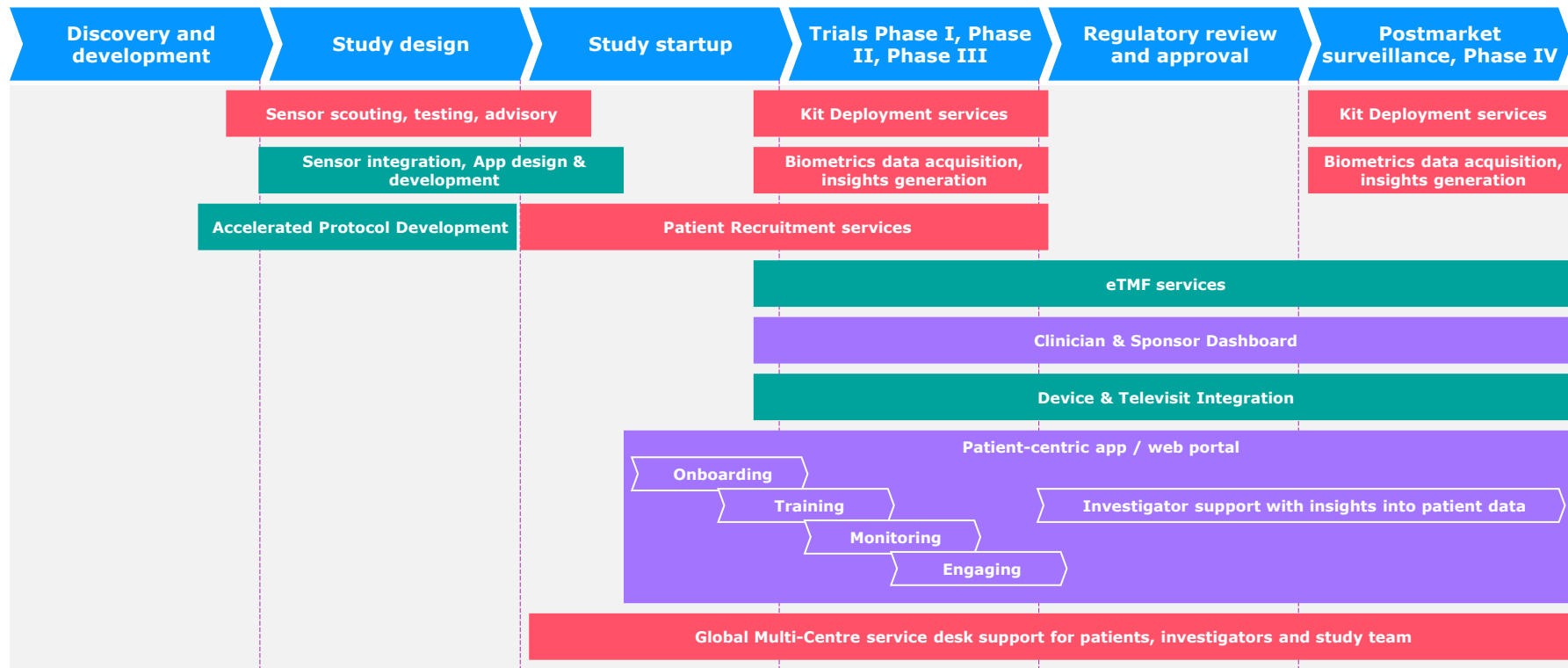


Operational savings: Focus on **managing the studies in a "worry-free" manner**

- **45-60%** less **administrative time**
- **15-25%** lower **handling & distribution costs**
- **35%** lower **enrollment costs**

Atos' coverage of the Clinical Trial Process...

the most critical part of Drug Research & Development, and early Commercialization



Green Solutions and services delivered by Atos

Purple Solutions and services delivered by Atos with partners' involvement

Red Today's focus

Patient Recruitment services

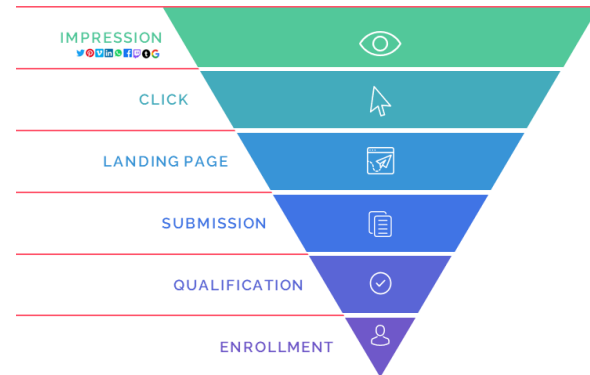
Opening alternative reach out channels to secure and speed up recruitment

Atos and partners' experience



- +20'000 Patients enrolled (11'000 in last 12 months)
- +50 studies (interventional, observational, and registries)
- Achieved 3-times industry standard enrollment rate
- Strong industry partnerships and track record with DCT players and CROs
- 9 DCT studies currently underway
- 90% of On time enrollment (industry standard: 14% on-time)
- Proprietary technology for precision targeting
- Proven 4x more engagement vs. standards
- +20 Therapeutic Areas (Women & Men's Health, Immunology, Pulmonary, Dermatology, Cardiology, Renal)
- Markets: Eastern Europe, Western Europe, North America, APAC, LATAM

Leveraged frameworks



Customer benefits



- 100% On time / On budget enrollment
- Full GDPR compliant across all patient communication touchpoints



Faster and more targeted recruitment (example: 6 weeks vs. 5-6 months originally forecasted)



35% lower enrolment costs



Atos

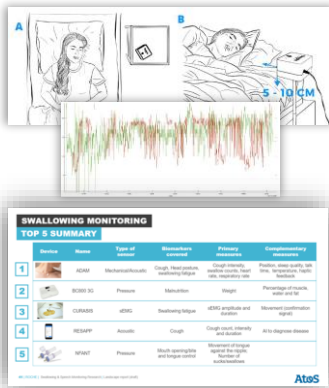
Sensor scouting, selection, testing & integration services

To increase product diversification, increase value delivered to healthcare systems

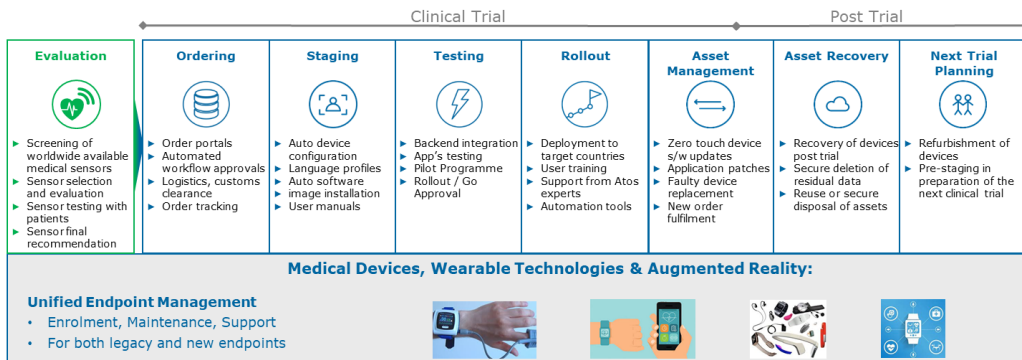
Atos experience



- Market scouting for specific sensors to be used for digital biomarkers
- Evaluation of sensors recommending the best one
- Field-test the sensor with patients/ sensor qualification
- Sensor integration into the clinical trial program, incl. App development
- Ensure sensor data collection, analytics and analysis for insights captured by the sensors
- Autism, Indoor patient location, Repetitive patient movements, Anxiety, Sleep monitoring, Swallowing, Breathing, Infant spasm



Leveraged framework



Customer benefits

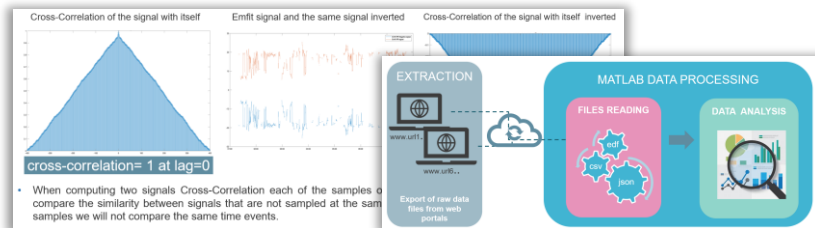


- Leverage data-driven digital biomarkers to complement study results
- Precise, qualified sensor application based on customer requirements (in any TA, any specific modalities)
- Coverage of the End-to-End assets' lifecycle management
- Focus on 1-3 months implementation



30% faster sensor-to-study

TA: therapeutic area



Biometrics data acquisition, insights generation

To deliver faster and more precisely on personalized medicine needs

Atos experience

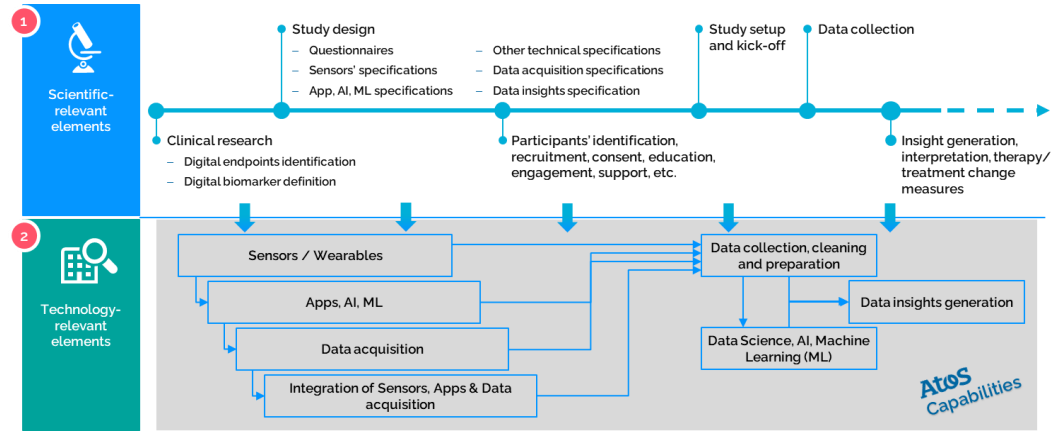


- Wrap digital technologies & services around the pill
- Implementation of e.g., Adherence services, Mobile health services, Reimbursement support, Medication tracking, Communities, Indication repository, Nutrition / diet, Fitness, Wearables / Medical devices, Digital therapeutics, etc.
- App development or integration in existing Apps

SWALLOWING MONITORING					
TOP 5 SUMMARY					
Rank	Device	Name	Type of sensor	Primary indication	Implementation status
1	ADAM	Medication	Single swallow monitoring (light)	Single swallow monitoring (light)	Single swallow monitoring (light)
2	BCSD 30	Pharmaceutical	Swallowing	Weight	Percentage of meals, water intake
3	CLIMAX	AI/ML	Swallowing (light)	AI/ML analysis and AI/ML	Swallowing (light)
4	REDAV	Acoustic	Swallow	Single swallow, intensity and AI/ML	AI/ML analysis and AI/ML
5	NPAT	Pharmaceutical	Single swallow and single swallow	Single swallow and single swallow	Single swallow and single swallow

SWALLOWING MONITORING					
ADAM (SONICAREHEALTH)					
Company maturity	Non-profit Medication (Swallowing) (Swallowing) (Swallowing) (Swallowing) (Swallowing)				
Commercial availability & conditions	Not available (Swallowing) (Swallowing) (Swallowing) (Swallowing) (Swallowing)				
Technology suitability	Not available (Swallowing) (Swallowing) (Swallowing) (Swallowing) (Swallowing)				
Deployment feasibility	Not available (Swallowing) (Swallowing) (Swallowing) (Swallowing) (Swallowing)				
Remote monitoring	Not available (Swallowing) (Swallowing) (Swallowing) (Swallowing) (Swallowing)				
Supply chain	Not available (Swallowing) (Swallowing) (Swallowing) (Swallowing) (Swallowing)				

Leveraged framework



Customer benefits



- Expanding R&D scope to adjust for product diversification elements positively impacting market access and competitive situation
- A pragmatic framework to add digital therapeutics supported by specific Apps, drive superior value creation, innovation, additional patients' services
- Clear view / data on the target patient, patient journey, indication dynamic, pain points, white-spots, digital phenotyping
- Possibility for fast verification of additional options / hypothesis / ideas in the field, with a data-driven approach



30% faster digital service-to-market



Atos

Global Multi-Center service desk support

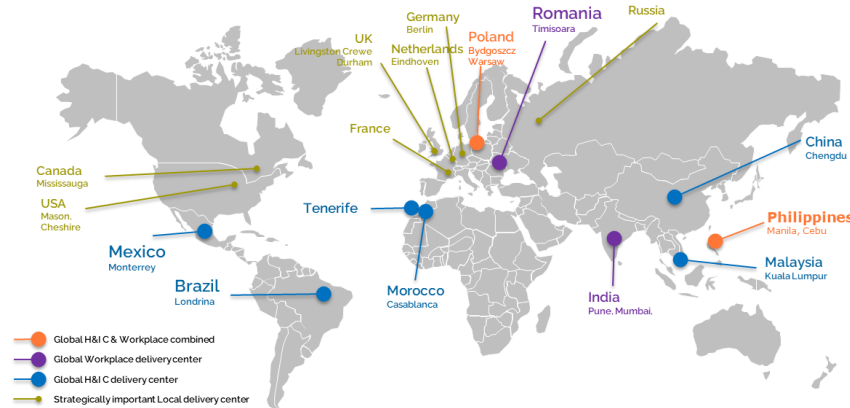
To support patients, investigators and study teams

Atos experience



- Serving 30+ clinical trials in over 50 countries
- Supporting 38 different languages
- Over 3 million users using the service at a given point in time
- Managing over 3 million devices worldwide
- Driving support onsite in 115 countries
- High-level of process automation
- Inclusion of nurse and medical doctor personnel
- Covering therapeutic areas as e.g., oncology, mental health, cardiovascular diseases, rare diseases, women health
- Patient engagement programs with high-level of regular iterations
- Omnichannel experience with large adoption of non-voice channels, such as self service and chat

Leveraged locations



38 languages supported

31 million resolved user tickets annually

> 3 million users supported globally

3.2 million managed user devices worldwide

Onsite Support capabilities in 115 countries

Customer benefits



- Highly cost competitive compared to internal call centers
- Superior, 5 Stars-rated patient experience from the first iteration and throughout the study
- Over 90% adherence
- Consulting on best practice for patient engagement programs
- Flexibility to adapt to immediate study needs (possible scale up and down on a monthly basis)
- Fast scalability to cover diverse combination of clinical studies in multiple countries, worldwide
- Possible integration with customer internal call-center

Supported Primary Languages		
English	Portuguese	Cantonese
French	Italian	Mandarin
German	Polish	Malaysian
Spanish	Russian	
Supported Secondary Languages		
Arabic	Hindi	Serbian
Bulgarian	Hungarian	Slovenian
Croatian	Indonesian	Swedish
Czech	Japanese	Thai
Danish	Korean	Turkish
Dutch	Norwegian	Ukrainian
Finnish		Vietnamese

Atos

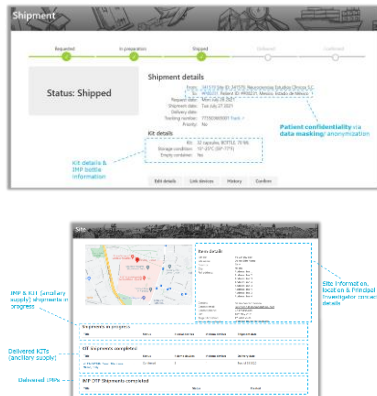
Kit Deployment services

To simplify clinical trial operations, increase operations' flexibility, by lowering costs

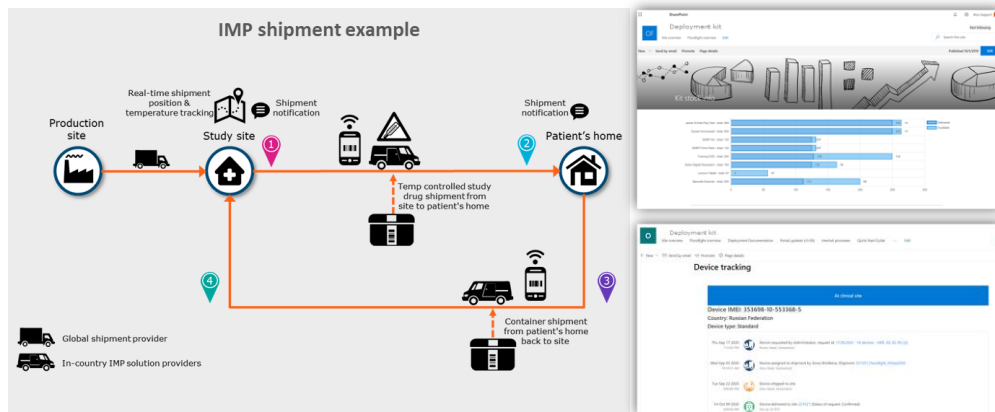
Atos experience



- All operations around ordering and setting up of all contents of the kits (digital, medical, IMP)
- Worldwide distribution up to the patient home
- Deliver to all stakeholders of one integrated / consistent and compliant platform
- Worldwide, compliant home delivery and collection in (actually) 53 countries, export / import regulations' knowledge
- *30 clinical trials served so far



Leveraged framework

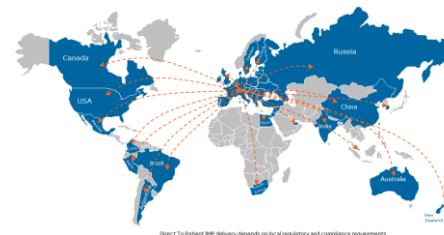


Customer benefits



- 45-60% less administrative time of sponsor team
- 15-25% lower handling and distribution costs
- Clinical Trial Kit Deployment with one partner, one integrated platform, flexibility to adapt for changing trial's needs
- *New site activated in 2-3 days; *New patient cohort in 5-7 days
- Exact, reliable tracking of kits and IMPs
- Better prediction of study performance

*Depends on country / site specific regulations



- Global IMP services across 53 countries
- Temperature-controlled transportation
- Local temperature-controlled warehouses
- Adherence to local regulatory compliance rules
- End-to-End Track & Trace of IMP deliveries

Atos

Digitization of Kit Deployment services at a Top 3 global Pharma

To simplify clinical trial operations, increase operations' flexibility, by lowering costs

Which business issue was addressed?

- Clinical studies are instrumental to receive regulators' approval for any medicine or treatment. The worldwide deployment of the patients' kits (including Apps, phone, sensors, instructions, trainings, and the medicine itself) plays a critical part and require a high operational flexibility and large number of partners
- The sourcing, testing, integration and shipment of all the equipment and material in heavy-compliance countries is costly and time consuming
- Clinical study for treatment of Relapsing Multiple Sclerosis (RMS), conducted with approx. 280 sites across more than 32 countries

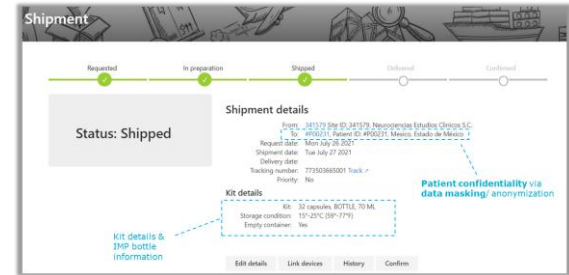
What was Atos proposing?

- Cover all operations around ordering and setting up of all contents of the kits (digital, medical)
- Worldwide distribution up to the patient home
- Deliver to all stakeholders of one integrated, consistent and compliant platform (one partner, one integrated platform, flexibility to adapt for changing trial's needs)
- Worldwide, compliant home delivery and collection in heavy-compliance countries, export / import regulations' knowledge
- 45-60% less administrative time and 15-25% lower handling and distribution costs

Win facts & figures

- Non-competitive, 0,7MCHF TCV contract (>50% margin), following a multi-million engagement
- During the study timeline, typically change requests are initiated to new site activation or new patient cohort in the measure of 40-60% TCV
- On top of this engagement, additional clinical studies operations are expected with minimum TCV: 2-3MCHF per year

Pursue key contributors



Atos

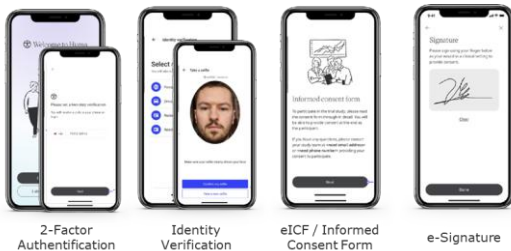
Patient-centric app / web portal

To increase patient engagement, avoid drop out and foster protocol adherence

Atos and partners experience



- Optimized HCP experience and consumer-friendly patient experience
- Flexible integration via industry standards HL7-FHIR, openEHR, DICOM, SAML, etc.
- Edge, Hybrid, or cloud deployment in-line with local requirements
- Superior security including end to end encryption
- Differentiating AI and AR capabilities



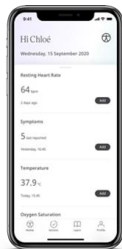
2-Factor Authentication

Identity Verification

eICF / Informed Consent Form

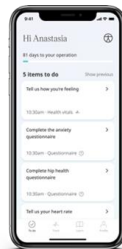
e-Signature

Leveraged framework



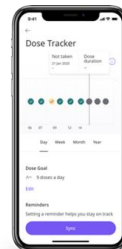
Data collection

Library of core & 3rd-party modules to track & monitor disease symptoms & participant behaviors e.g. activity tracking and PROs



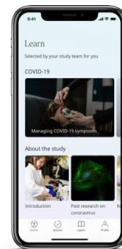
Scheduling & reminders

Provide notifications and reminders to prompt and ensure participants complete assessments as per the trial protocol.



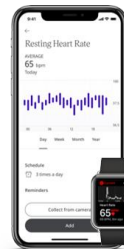
Medication tracker

Guide participants through use of medication and provide reminders on when to take/record at home medication use or return to the clinic for their treatment



Educational / learn content

Customized educational content, ensuring clear expectations are communicated & participants feel supported and valued



Device integration

Device agnostic with the ability to capture data from 400+ connected devices, wearables, and sensors



Telemedicine / video visit

Telemedicine solution enables investigators to promptly support participants remotely, reducing clinical site visits and improving patient experience

Customer benefits



Superior experience for patients

- eConsultations including pre, in, and post hospital stay, clinical trials
- Appointment scheduling and rescheduling
- AI & ML analysis of Visual symptoms
- Guided Triage
- End-to-End security

Superior experience for investigators

- Tailored Workflows for eConsultation, Home Care, Patient Flows, Resource Orchestration, Tracking and Utilization
- Orchestration and integration of EHR systems, Appointment systems, Identity Providers, Customer Experience solutions
- Service Integration and Management
- End to end security

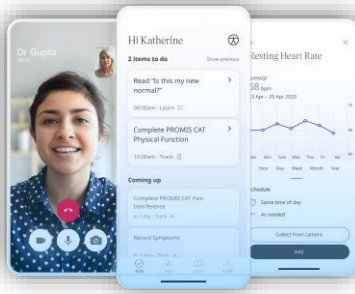
Device & Televisit Integration

To secure optimal remote medical services

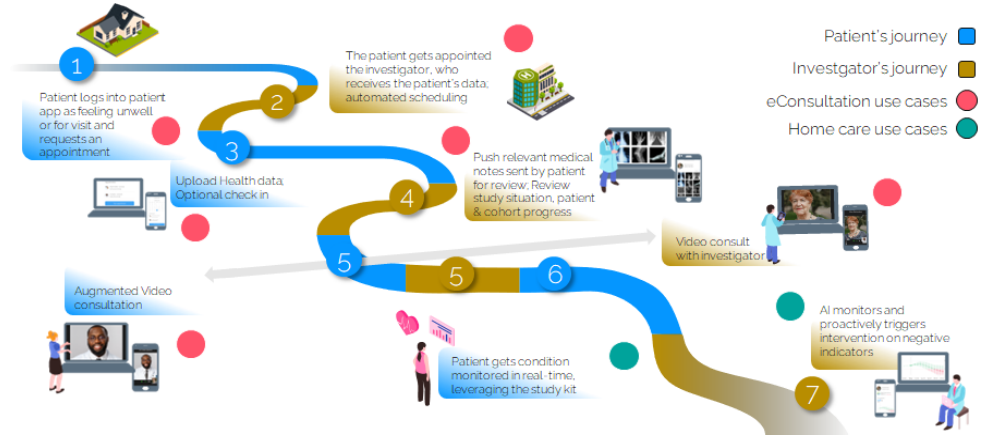
Atos experience



- Optimized practitioner experience
- Consumer-friendly patient experience
- Flexible integration via industry standards HL7-FHIR, openEHR, DICOM, SAML, etc.
- Edge, Hybrid, or cloud deployment in-line with local requirements
- Superior security including End-to-End encryption
- Life cycle services
- Differentiating AI and AR capabilities



Leveraged framework



Customer benefits



Superior experience for patients

- eConsultations including pre-, in-, and post-hospital stay, clinical trials
- Appointment scheduling and rescheduling
- AI & ML analysis of Visual symptoms
- Guided Triage
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Superior experience for investigators

- Tailored Workflows for eConsultation, Home Care, Patient Flows, Resource Orchestration, Tracking and Utilization
- Orchestration and integration of EHR systems, Appointment systems, Identity Providers, Customer Experience solutions
- Service Integration and Management
- End to end security

Clinician & Sponsor Dashboard

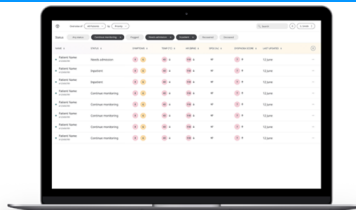
To manage, monitor and engage the participants' cohort, comprehensive data visibility

Atos and partners experience



- Web-Based dashboards
- Near real-time access to patient generated data & insights for clinicians, CROs & sponsors
- Power one of the largest multinational decentralized clinical trials
- Multiple successful deployments in care settings with established PI/trialist relationships
- Global, dynamic platform with ability to add new languages rapidly
- AI and data sciences expertise to deliver novel biomarkers with extensive library of data collection modules

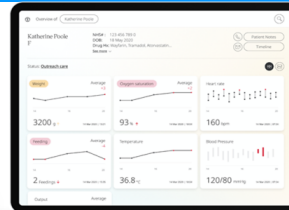
Leveraged solutions



Cohort dashboard

Physicians manage multiple patients within a centralised web-based dashboard allowing for flagging and prioritisation of patients from data generated through the Huma app

MANAGE



Individual participant dashboard

Specific patients/ participants may also be monitored through an individual patient dashboard view to track overall biometric vital signs, care planning and timelines

MONITOR



Telemedicine dashboard

Direct patient / participant communication is enabled within a physician's dashboard to allow for improved patient-physician engagement via telemedicine and remote monitoring

ENGAGE

Customer benefits



- Investigator support with insights into patient data
- Rapidly assessment of a patient's condition remotely
- Remote clinical supervision (advise and observe local nurses)
- Audit log of calls and their duration
- Reduced ambulance admissions and costs
- Better patient outcomes
- De-identified patient data generated for sponsor and CROs
- Live, on-demand data access and export by study sponsor
- Multiple stakeholder data viewing with role-based access controls



Digital Twin to simulate the patient condition

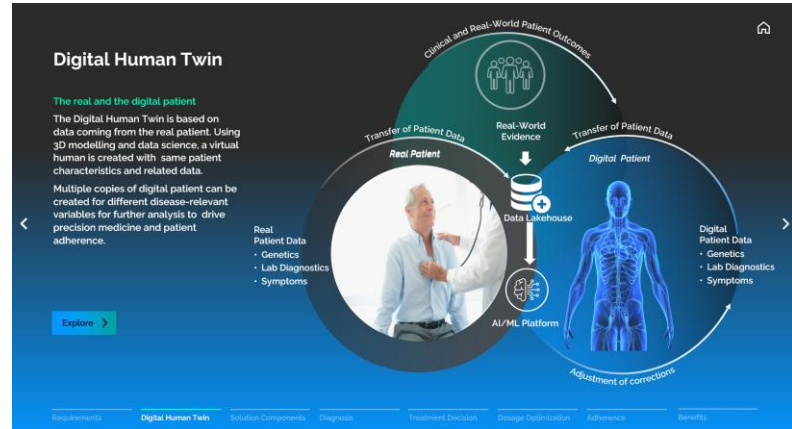
Increasing patient adherence in any indication, increasing product sales

Atos experience



- Digital Health Solutions, incl. Prescription DTx, Consumer Health OTC, Digital Diagnostics, Digital Medicine, Digital Companion, and Remote Patient Monitoring
- Large number of Digital Twin application in production and supported by a dedicated Center of Excellence
- Patient / User-centric format, design and personalized services
- Solution of patient challenges across payer, provider, and life sciences value chains
- Digital Twin design within 4-7 weeks, validation and design adjustment 3-4 weeks, MVP Operationalization 1-2 months
- Certified to ISO 13485: 2016 for design and development of medical device systems and subsystems
- Compliant to the FDA Quality System Regulation (CFR Part 820 for medical devices)

Leveraged framework



Customer benefits



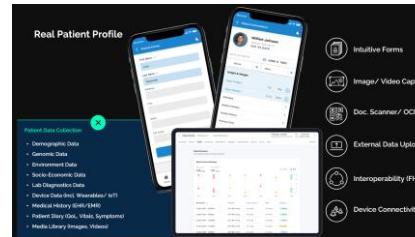
- Digital Twin customizable for different indication
- Further customization based on single patient situation
- Inclusion of Real-World Evidence data and customer data



45-60% revenue increase due to increased adherence



10-20% increased overall product value-add for healthcare systems



eTMF services

To reduce Time-to-Market, increase documentation quality, by lowering costs

Atos experience



- eTMF implementation (GxP validation), integration, documents migration, hyper care, and on-going steady state support
- 5+ Platform Implementation
- 10+ Global Top Pharma, Biotech customers
- 10+ ECM / eTMF Platforms experience
- 12+ years TMF Experience
- 690+ FTEs specialized TMF Team
- 2100+ FTEs Document Management Team
- 2500+ Clinical studies supported
- 25 Million Clinical / eTMF documents processed, 1400+ document types
- eTMF tool agnostic Intelligent Document Processing and RPA

Leveraged framework



TMF Consulting	TMF Operations (Paper & Electronic)	TMF Governance	IT Services	Transformation Services
Change Management	Digitization of pTMF	TMF Oversight	eTMF Tool Implementation & Maintenance	AI, ML, NLP, Big Data Enabled Process Automation
Regulatory Consulting	Archival/Retrieval Requests Handling	Quality Management	Integration & Migration Support	Automated eTMF Metadata Extraction
Technical Redesign	M&A Support for In- / out-licencing	Audit and Inspection Support	Cloud Enablement	Independent Quality Control (Closed & Ongoing Studies)
Digital Transformation	eTMF Operations	Pharma Regulations Compliance	M&A Support	RPA Based Document Upload
Submission Support				

Regulatory Compliance: GxP, GDP, 21 CFR Part 11

Customer benefits



25-40% productivity gain by applying automation, process optimization, standardization



32% of cost reduction due to process simplification and automation



40% reduction in documents Turn Around Time (TAT)

- 99.2% of quality accuracy by reducing human errors
- Improved compliance
- Refocus clinical operations staff on higher value activity
- Fast service implementation (within 6 to 8 weeks)



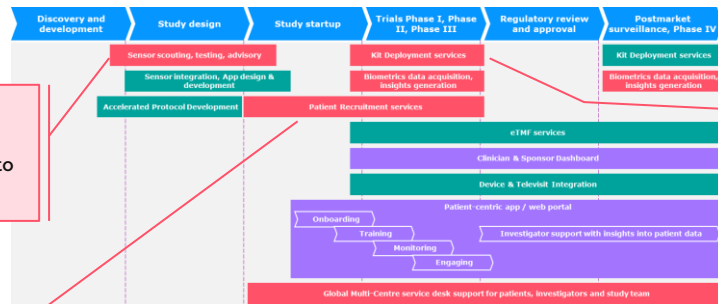
45-60% less administrative time of sponsor team

Global Coverage

- ▶ **73** Offices Worldwide including **13** Global Delivery Centers
- ▶ Coverage in North America, Latin America, Europe, UK, Japan, APAC, Middle East.
- ▶ **50+** CRO Countries Coordination

Next steps to proof the value, ...

... by jointly preparing a high-level Business Case for an upcoming clinical study



Assumption: four Atos services for proof of value

1. Patient Recruitment
2. Kit Deployment
3. Sensor scouting and selection
4. Multi-Centre service desk support

Atos suggestion



Joint plan



Identify an upcoming clinical study and nominate a SPOC for next steps

- 1,5-2 weeks from study details to proposal
- Proposal and approach presentation
- Decision, and operationalization

SPOC: Single Point of Contact

Thank you

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