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ARIA digital anamorphosis: Digital transformation of health and care in airway diseases from research to practice

Item Type	Article
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	<p>Mösges R, Münter L, Muraro A, Murray R, Naclerio R, Napoli L, Namazova-Baranova L, Neffen H, Nekam K, Neou A, Nordlund B, Novellino E, Nyembue D, O'Hehir R, Ohta K, Okubo K, Onorato GL, Orlando V, Ouedraogo S, Palamarchuk J, Pali-Schöll I, Panzner P, Park HS, Passalacqua G, Pépin JL, Paulino E, Pawankar R, Phillips J, Picard R, Pinnock H, Plavec D, Popov TA, Portejoie F, Price D, Prokopakis EP, Psarros F, Pugin B, Puggioni F, Quinones-Delgado P, Raciborski F, Rajabian-Söderlund R, Regateiro FS, Reitsma S, Rivero-Yeverino D, Roberts G, Roche N, Rodriguez-Zagal E, Rolland C, Roller-Wirnsberger RE, Rosario N, Romano A, Rottem M, Ryan D, Salimäki J, Sanchez-Borges MM, Sastre J, Scadding GK, Scheire S, Schmid-Grendelmeier P, Schünemann HJ, Sarquis Serpa F, Shamji M, Sisul JC, Sofiev M, Solé D, Somekh D, Sooronbaev T, Sova M, Spertini F, Spranger O, Stellato C, Stelmach R, Thibaudon M, To T, Toumi M, Usmani O, Valero AA, Valenta R, Valentin-Rostan M, Pereira MU, van der Kleij R, Van Eerd M, Vandenplas O, Vasankari T, Vaz Carneiro A, Vezzani G, Viart F, Viegi G, Wallace D, Wagenmann M, Wang Y, Wasserman S, Wickman M, Williams DM, Wong G, Wroczynski P, Yiallourous PK, Yusuf OM, Zar HJ, Zeng S, Zernotti ME, Zhang L, Shan Zhong N, Zidarn M. ARIA digital anamorphosis</p>
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DOI	10.1111/all.14422
Publisher	Wiley
Journal	Allergy
Rights	Attribution 3.0 United States
Download date	2026-04-13 14:43:44
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This article has been accepted for publication and undergone full peer review but has not been through the copyediting, typesetting, pagination and proofreading process, which may lead to differences between this version and the [Version of Record](#). Please cite this article as [doi: 10.1111/all.14422](https://doi.org/10.1111/all.14422)

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482 **Short title : Digital transformation of care in rhinitis**

483

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492 **Abstract**

493 Digital anamorphosis is used to define a distorted image of health and care that may be viewed correctly
494 using digital tools and strategies. MASK digital anamorphosis represents the process used by MASK to
495 develop the digital transformation of health and care in rhinitis. It strengthens the ARIA change
496 management strategy in the prevention and management of airway disease. The MASK strategy is based on
497 validated digital tools. Using the MASK digital tool and the CARAT online enhanced clinical framework,
498 solutions for practical steps of digital enhancement of care are proposed.

499

500 **Key words:** asthma, digital transformation of health and care, rhinitis, MASK, ARIA, CARAT

501

502 **Abbreviations**

503 AIRWAYS-ICPs: Integrated care pathways for airway diseases

504 AIT: Allergen immunotherapy

505 AR: Allergic rhinitis

506 ARIA: Allergic Rhinitis and its Impact on Asthma

507 CARAT: Control of Allergic Rhinitis and Asthma Test

508 CDSS: Clinical decision support system

509 DB-PC-RCT: Double-blind, placebo-controlled, randomized trial

510 EFA: European Federation of Allergy and Airways Diseases Patients' Association

511 EIP on AHA: European Innovation Partnership on Active and Healthy Ageing

512 EIT: European Institute for Innovation and Technology

513 EQ5D: Euroquol

514 EU: European Union

515 GA²LEN: Global Allergy and Asthma European network

516 GARD: Global Alliance against Chronic Respiratory Diseases

517 GRADE: *Grading of Recommendations* Assessment, Development and Evaluation

518 ICP: Integrated care pathway

519 IT: Internet technology

520 JA-CHRODIS: Joint Action on Chronic Diseases and Promoting Healthy Ageing across the Life Cycle

521 MACVIA: Fighting chronic diseases for active and healthy ageing

522 MASK-air[®]: (formerly Allergy Diary)

523 MASK: Mobile Airways Sentinel Network

524 MeDALL: Mechanisms of the Development of Allergy

- 525 POLLAR: Impact of air POLLution on Asthma and Rhinitis
- 526 QOL: Quality-of-life
- 527 RCT: Randomized controlled trials
- 528 RWD: Real-world data
- 529 RWE: Real-world evidence
- 530 SCIT: Subcutaneous immunotherapy
- 531 SLIT: Sublingual immunotherapy
- 532 SMS: Symptom-medication score
- 533 TRL: Technology Readiness Level
- 534 TWINNING: Transfer of Innovation
- 535 WHO: World Health Organization
- 536

537 Introduction

538 Anamorphosis - from the Greek *αναμόρφωση*: *transformation* - is used in several fields to describe the
539 transformation of a distorted object (e.g. painting, architecture, entomology, biology). Digital technology
540 reveals the day-to-day experience of patients and provides a new type of information that – when properly
541 collected and interpreted - will restore the real expression of the disease. In this paper, anamorphosis is
542 used to define a distorted image of health and care that may be viewed correctly using digital tools and
543 strategies.

544 The strategic overview (Table 1, Figure 1 online) and the vision of MASK included several considerations
545 (Table 2). The disease burden and the healthcare costs for people with allergic and chronic respiratory
546 diseases are increasing rapidly (1). The transformation of the healthcare system for integrated care through
547 leveraging developments in digital health is urgently needed (2). The term “digital health” includes
548 advanced medical technologies, disruptive innovations and digital communication tools aiming to provide
549 best practice healthcare (3). Smart devices and internet-based applications are largely used in airway
550 diseases and are likely to address certain unmet needs (4). However, these new tools need to be tested: (i)
551 for privacy rules, security, and legislation of the Medical Device Regulation (May 2020); (ii) for
552 acceptability, usability and cost-effectiveness (5) and (iii) for validity. They should then be evaluated in the
553 frame of the overall digital transformation of health and care, their impact on healthcare delivery as well as
554 health outcomes. mHealth tools and strategies enabling the digital transformation of health and care,
555 empowering citizens and building a healthier society represent a novel important step in health care.
556 However, a practical integrated approach is required.

557 In 2014, on behalf of the European Innovation Partnership on Active and Healthy Ageing (EIP on AHA)
558 (6), AIRWAYS ICPs (Integrated Care Pathways for airway diseases) was initiated (7, 8). The objective was
559 to launch a collaboration to develop multi-sectoral care pathways (ICPs) for chronic respiratory diseases in
560 European countries and beyond as a Global Alliance Against Respiratory Diseases (GARD) demonstration
561 project (Figure 1). MASK (Mobile Airways Sentinel Network) is the mHealth strategy of AIRWAYS ICPs
562 and ARIA (9). It was based on the ARIA study group existing in 92 countries. MASK is deployed in 26
563 countries and 17 languages. MASK, as a practical ICT integrated approach, was initially developed as an
564 app (MASK-air®) and is now an e-platform for allergic diseases and asthma.

565 The Control of Allergic Rhinitis and Asthma Test (CARAT) is a Patient-Reported Outcome that assesses
566 the level of control of both asthma and AR using a single tool (10). It enables the implementation of the
567 ARIA recommendations in the simultaneous assessment and management of both allergic rhinitis (AR) and
568 asthma (11).

569 This paper proposes the ARIA change management strategy in the prevention and management of airway
570 disease (12). MASK digital anamorphosis represents the process used by MASK to develop the digital
571 transformation of health and care in rhinitis. It also strengthens ARIA change management. Using the
572 MASK digital tool and the CARAT online enhanced clinical framework, solutions for each practical step of
573 digital enhancement of care are provided.

574 **Digital transformation of health and care in rhinitis and asthma** 575 **multimorbidity**

576 **The MASK e-platform**

577 MASK, the Phase 3 ARIA (Allergic Rhinitis and its Impact on Asthma) initiative (11, 13) is a Good
578 Practice of DG Santé for digitally-enabled, patient's centered care (14). It has been developed from the
579 MASK-air® app to a flexible e-platform for allergic diseases and asthma. It includes: (i) a freely available
580 app (MASK-air®, formerly the Allergy Diary, Android and iOS) (13), (ii) tools to support health care
581 professionals in shared decision making through an interoperable electronic decision support system (e-
582 CDSS) (15), (iii) a web-based interoperable questionnaire for physicians (16), (iv) a questionnaire on
583 asthma and rhinitis (CARAT) for screening allergic diseases and assessing their control and (v) a sentinel
584 network for air quality and pollen seasons. Other tools can be added when needed.

585 The maturity level of the MASK Good Practice is presented in Table 3, and Table 1 online.

586 MASK is scaled up using the European Innovation Partnership on Active and Healthy Ageing (EIP on
587 AHA) strategy (16, 17).

588 **MASK-air®**

589 **Characteristics**

590 MASK-air® is an ICT (Information and Communication Technology) system centered around the patient
591 (18). It is operational in 25 countries and 18 languages. It uses a treatment scroll list which includes all of
592 the medications customized for each country. Furthermore, a visual analogue scale (VAS) assesses rhinitis
593 control (global allergy impact, nose, eyes, asthma), sleep and work productivity (19, 20). MASK-air® is
594 combined with prediction on allergen season and air quality (POLLAR: Impact of POLLution on Asthma

595 and Rhinitis, EIT Health-funded project) (21). MASK is available in 26 countries and 17 languages
596 including some middle-income countries (Table 2 online). Patients' organizations and scientific societies
597 are involved.

598 **Privacy, General Data Protection Regulation (GDPR) and Medical Device** 599 **Regulation (MDR)**

600 The General Data Protection Regulation (GDPR) regulates the processing of personal data in the European
601 Union (EU) (22, 23). MASK-air[®] follows the five main principles of personal data protection to be
602 respected during the development of the app: purpose, proportionality and relevance, limited retention
603 period, security and confidentiality, as well as the rights of the people who are involved in the management
604 of the personal data (including withdrawal and modification) (24). Moreover, MASK-air[®] uses k-
605 anonymity for geolocation (25). A double encryption database has been set up.

606 MASK-air[®] is currently a Class 1 Medical Device but it will be upgraded to Class 2A with the new MDR to
607 be enforced in the EU in May 2020 (26).

608 **Validation**

609 There are absolute pre-requisites for the launch of an app. They include:

- 610 • Questions of MASK-air[®] were validated by patients (Madopa and STIMCO, unpublished) and are
611 easily understood by patients in different countries.
- 612 • MASK-air[®] followed COSMIN (COnsensus-based Standards for the selection of health Measurement
613 Instruments) guidelines (27).
- 614 • The independence of data has been confirmed (28).
- 615 • Translations have been validated using a back translation.
- 616 • MASK-air[®] has been implemented in the different situations in which it is used (14, 15, 18, 24, 27-37)
617 .

618 **CARAT**

619 CARAT (Control of Allergic Rhinitis and Asthma Test) is a validated questionnaire that can summarize the
620 clinical status of asthma and rhinitis (multimorbidity) of the previous 4 weeks. It complements the
621 frequent/daily self-assessment in the MASK-air app and the physician's clinical assessment.

622 **Characteristics**

623 The CARAT questionnaire has two domains: allergic rhinitis and asthma and 10-items regarding
624 symptoms, sleep, activities and drug use within the past 4 weeks (38). CARAT's minimal clinically
625 important difference can detect change over time (high responsiveness) (39). CARAT supports shared
626 decisions between the patient and the physician as well as within the healthcare team. CARAT has been
627 used in 19 countries globally including developing countries (40).

628 CARAT can be used in a range of different aims: (i) screening of patients with rhinitis or asthma in
629 different setting including pharmacies (41), (ii) follow-up consultations together with lung function (42),
630 (iii) patient self-management (43) and (iv) identifying patients with uncontrolled asthma at pharmacies
631 (41). It should increase awareness of the level of disease control and strengthen the partnership between
632 patients and doctors in the management of asthma and rhinitis by helping to define shared treatment goals.

633 CARAT has been used in epidemiology and clinical research (44): it has been included in international
634 multicentre studies, such as the technology transfer of innovative practices (Twinning) project (16) and the
635 observational longitudinal multicentre prospective study, the “@IT2020” study (45). CARAT has been
636 implemented as a mHealth tool in several smartphone applications including MASK-air (18),
637 InspirerMundi (46), the Adolescent Adherence Patient Tool (ADAPT) app (47), and Lung Manager (48).

638 **Validation**

639 CARAT has been thoroughly studied in cross-sectional and prospective studies conducted at all levels of
640 MASK Care Pathways. It meets all COSMIN criteria for patient reported outcome (49).

641 CARAT has been used in clinical studies and in clinical practice. It has enabled comparison between
642 groups as well as evaluation of individual patients over time (10, 38). The questionnaire has been deployed
643 in patient care and/or research. CARAT has been implemented in different settings (Pharmacies, Primary
644 Care, Secondary Care, epidemiology and clinical research) and technologies including mHealth tools (18,
645 41, 44, 46, 47, 50-52), but also in severe asthma in specialists (53).

646 **New functionalities**

647 CARAT has the potential to evolve to further strengthen multimorbidity assessment and to focus on more
648 severe patients. This change can be carried out simply by reassessing questions that were excluded during
649 the initial developing process (10). In particular, eye symptoms should be included as, within the

650 asthma-rhinitis multimorbidity, they are associated with more severe phenotypes as demonstrated by the
651 MASK-air app (33) and confirmed by an epidemiologic study with full medical observation (40).

652 **Electronic clinical decision support system (eCDSS) for rhinitis**

653 The interoperable electronic decision support system (eCDSS) (15) is based on an algorithm designed by
654 the ARIA expert group (54) and validated using real-world evidence (55). This eCDSS is to be used on
655 tablets by pharmacists and physicians.

656 **Web-based physician's questionnaire for rhinitis and asthma**

657 An interoperable questionnaire for physicians is available online on the Euforea website
658 (<https://www.euforea.eu>). Around 1,000 patients have been enrolled in the rhinitis-TWINNING using the
659 questionnaire. They are then followed up using the MASK-air[®] app (16).

660 **Sentinel network for air quality and pollen prediction**

661 POLLAR confirmed the interactions between air pollution, asthma and rhinitis in order to propose the
662 prediction of these environmental factors in MASK-air[®] (21, 36). It uses the MASK-air[®] app combined
663 with a new tool allowing queries on pollen and air quality, in geolocalized patients. Allergic symptoms of
664 the MASK-air[®] app are integrated with the Symptom Forecasting Model developed within the PASYFO
665 project of Copernicus Atmospheric Monitoring Service, which also supplies the meteorological, air quality
666 and pollen information for Europe. Additional pollen and global air quality forecasts are generated by the
667 SILAM model of the Finnish Meteorological Institute (FMI) (56-58). Machine learning will be used to
668 assess the relationship between air pollution, AR and asthma to further refine the prediction.

669 **Patients' views**

670 Many patients do not understand the needs and benefits of mHealth and may worry about data privacy
671 (Table 3). Thus, the uptake of mHealth is slow. On the other hand, too many patients over-rely on internet-
672 based information and on untested mHealth solutions. This attitude may have dangerous implications since
673 patients may receive an incorrect diagnosis or management strategy.

674 **Features required to satisfy patients.**

675 A qualitative study was carried out by MADOPA in 2016 for MASK to better understand the patients'
676 needs and expectations (Table 4).

677 **Implementation and communication strategy for patients**

678 Without a communication strategy, the app will not be largely used. However, the communication plan will
679 only be put in place for 2020 once the POLLAR module has been added. Documents are available in 17
680 languages and can be downloaded from the MASK website (<https://www.mask-air.com>). They include
681 leaflets for patients, physicians and pharmacists as well as other documents. In Mexico, this strategy was
682 found to be effective. It will be deployed to other countries.

683 The communication strategy must involve local patient's organizations. It will be deployed with
684 the patients' organization EFA. The importance of patients' associations has always been recognized in
685 ARIA. For the digital transformation of health and care, they are even more important. The following
686 messages sent by the app need to be reinforced for the patients:

- 687 • Better understanding of the symptoms.
- 688 • Sentinel network linking aerobiology data and control.
- 689 • Improved adherence.
- 690 • Self-management.
- 691 • Patient empowerment.

692 **MASK achievements in digital anamorphosis**

693 **Anamorphosis steps based on digital learning and Real-World Data**

694 MASK-air® has been used for 5 years and has evolved since its first inception. Major RWD results of the
695 MASK strategy (MASK-air®, POLLAR and CARAT) are presented in Table 5.

696 **Health outcomes**

697 In AR and asthma, a relevant outcome providing information on the cost-effectiveness of interventions is
698 needed. EQ-5D (EuroQol), a standardized and validated non-disease specific instrument to describe and
699 value health-related quality of life, has been used in allergic rhinitis (31, 59-64) but it cannot be used for
700 daily assessment. EQ-5D is one of the MASK-air[®] questionnaires (31). In MASK, VAS work correlates
701 with other MASK outcomes (VAS global, nose, eye and asthma) (28, 29) and should be considered as a
702 potentially useful allergic rhinitis outcome in intervention studies.

703 RWD make it possible health technology assessment.

704 **Use of real-world data to develop next-generation care pathways for**
705 **chronic respiratory diseases**

706 Care pathways are structured multi-disciplinary care plans detailing the key steps of patient care (7). They
707 promote the translation of guideline recommendations into local protocols and their application to clinical
708 practice. ICPs have been proposed with a focus on mHealth technologies that should enhance self-
709 management and adherence to guidelines and ICPs.

710 Next-generation care pathways for airway diseases follow the 2014 AIRWAYS integrated care pathways
711 (ICPs) concept (Figures 1 and 2) (55). As a proof-of-concept for chronic disease care, RWD obtained from
712 MASK provide a framework for real-life ICPs centred around the patient with rhinitis, using the mHealth
713 monitoring of environmental exposure. This is implemented in collaboration with professional and patient
714 organizations.

715 ARIA is constantly evolving and its most recent advance was determined following a meeting of
716 experts/stakeholders in Paris in December 2018 (65, 66) (Table 6). Three aspects of care pathways were
717 developed during this meeting: (i) Patient participation, health literacy and self-care through technology-
718 assisted “patient activation”, (ii) implementation of care pathways by pharmacists (67) and (iii) next-
719 generation guidelines assessing the recommendations of GRADE
720 (*Grading of Recommendations Assessment, Development and Evaluation*) guidelines in rhinitis and
721 asthma using RWE (55) and AIT (68). Next-generation guidelines for the pharmacologic treatment of
722 allergic rhinitis were developed using existing GRADE-based guidelines (69-71), RWD provided by
723 mHealth Apps (33, 35, 72) and additive studies (allergen chamber studies (73)) to refine the MACVIA
724 algorithm (54).

725 **Network of centers of excellence in digital health**

726 ARIA was established 20 years ago and includes more than 600 members in over 80 countries. In ARIA
727 Phase 4 (change management for airways diseases), a network of centres of excellence has been organized.
728 GA²LEN ARIACARE is one of the GA²LEN centres of excellence (74) and includes urticaria care
729 (UCARE) (75) and atopic dermatitis care (ADCARE). Accreditation follows the UCARE proposals.

730 ARIACARE-Digital is a novel network with the aim to implement the digital transformation of health and
731 care in airway diseases. Both members of MASK and others can join the network. ARIACARE-Digital has
732 links with GA²LEN but is a separate entity.

733 **Transfer of innovation (TWINNING)**

734 **Rhinitis-asthma TWINNING**

735 A transfer of innovative practices (TWINNING) (16, 76) was performed with the aim to transfer and
736 implement MASK-air[®]. The "Organization transferring the innovative practice" (originator organization)
737 had the experience and know-how developed in rhinitis and asthma IT solutions. The "Organization
738 adopting the innovative practice" (receiving/adopter organization) received the innovative practice and
739 implemented it in its territory. The rhinitis TWINNING was deployed from MASK to 22 countries. Around
740 1,000 patients were enrolled in the study. The phenotypic characteristics of rhinitis and asthma
741 multimorbidity in adults and the elderly were compared using validated information and communication
742 technology (ICT) tools (i.e. MASK-air[®], CARAT and a physician's questionnaire developed for the
743 TWINNING). This improved the understanding, assessment of burden, diagnosis and management of
744 rhinitis in the elderly by comparison with an adult population. The TWINNING was selected as a success
745 story.

746 **DigitalHealthEurope (DHE) Severe asthma TWINNING**

747 In order to reduce the burden of severe asthma with a focus on old age people, the objectives of the transfer
748 of innovation (DHE Severe Asthma TWINNING) are:

- 749 1. To form a European network for severe asthma in old age people globally (this does not currently
750 exist);
- 751 2. To better understand the phenotype and treatment of severe asthma with possible differences between
752 countries, age and gender;

753 3. To include the results into the MASK Good Practice for disease stratification and personalized health
754 care with a vision to optimize the prescription of expensive treatments (biologics) and to follow-up the
755 patients using RWD;

756 4. To be the basis for a further deployment beyond the funding including a network of centres of
757 excellence on severe asthma (ARIACARE and ARIACARE-Digital).

758 The DHE-TWINNING on SA (*Project acronym: H2020, DigitalHealthEurope Grant Agreement Number:*
759 *826353, Project full title: Support to a Digital Health and Care Innovation initiative in the context of*
760 *Digital Single Market strategy, Call identifier: SCI-HCC-05-2018*) was accepted September 16, 2019.

761 **Ongoing and future MASK actions**

762 **Advance capabilities: the same IT tool from epidemiologic studies to** 763 **clinical trials and clinical practice**

764 Symptom-medication scores (SMSs) are needed to investigate the effect of AR treatments, in particular
765 allergen immunotherapy (77). Several scores have been proposed and the European Academy of Allergy
766 and Clinical Immunology has designed one (78). However, a recent MASK analysis (28) has found that
767 this commonly-used SMS is not very well correlated with VAS work used as an end point. When
768 considering MASK data (72), it is possible that some patients with very high levels of VAS global (and
769 work) may not be able to be controlled with current pharmacologic treatments and a new SMS has been
770 proposed. This SMS for rhinitis has been validated with MASK-air® data. Other artificial intelligence
771 analyses are being carried out to obtain an optimal score.

772 Real-world evidence (RWE) combines results of double-blind, placebo-controlled, randomized trials (DB-
773 PC-RCT) and RWD. However, observational studies provide clinically-relevant information in addition to
774 DB-PC-RCT (33, 35, 72). RWD can provide new insights into disease patterns and help improve the safety
775 and effectiveness of health interventions. The same SMS will allow the comparison of the results of DB-
776 PC-RCTs and RWD in population studies or for the individual patient (79). This will provide
777 complementary information to DB-PC-RCTs and a real-life approach. Since patients are using the app and
778 the same system, it will be possible - using machine learning - to target the efficacy of AIT at the individual
779 level and to propose automatic advice to the physician for the indication of AIT as well as an early stopping
780 rule in clinical practice (68).

781 Patient stratification is an important step for expensive treatments such as allergen immunotherapy in
782 allergic diseases or biologics in severe asthma. There are currently no validated genetic or blood
783 biomarkers for predicting or monitoring the efficacy of treatments at an individual patient level in allergic
784 diseases (80). mHealth biomarkers (SMS) (68) and eCDSS (15) may change the scope of AIT in allergic
785 diseases or biologics in asthma or chronic rhinosinusitis.

786 **Towards severe asthma**

787 The lessons learnt by MASK will be used to build MASK-asthma which will include (i) a standardized
788 assessment of severity and control, (ii) the development of an upgraded e-platform for severe asthma
789 including screening, assessment by physicians and follow up, (iii) the analysis of MASK-air[®] data in file
790 for asthma, (iv) a pan-European IT-based alert system for exacerbations, (v) MASK-asthma IT tools for
791 registries and databases, (vi) transfer of innovation, (vii) a digital network of centres of excellence
792 (ARIACARE-Digital) and (viii) the development of next-generation care pathways for severe asthma.

793 **United perspective for chronic diseases to sustain planetary health**

794 Planetary health refers to "the health of human civilization and the state of the natural systems on which it
795 depends" (81). Most risk factors for non-communicable diseases (NCDs) are associated with Planetary
796 health.

797 Digital tools can also empower patients in the context of the UN sustainable development goals and in
798 particular regarding those related to sustainability and natural resources (82). Future apps in AR could
799 consider providing information to promote behavioural changes that could reduce the planetary impacts of
800 human activity.

801 During a conference entitled "Europe That Protects: Safeguarding Our Planet, Safeguarding Our Health"
802 co-organized by the Finnish Institute for Health and Welfare, the Finnish Environment Institute and the
803 European Commission under the auspices of Finland's Presidency of the EU in 2019, a symposium was
804 held to better understand the digital transformation of health and care to sustain planetary health in airways
805 diseases. The Finnish Allergy Programme is a proof-of-concept of Planetary Health and MASK (Mobile
806 Airways Sentinel Network), a Good Practice of DG Santé on digitally-enabled, patient's centered care
807 pathways, is in line with the objectives of the Finnish Allergy Programme.

808 Lessons learnt in rhinitis and asthma multimorbidity (18) can be deployed to other NCDs for change
809 management in health care. A uniform approach can be used (12) for the development of next-generation
810 care pathways in chronic diseases embedding the risk factors involved in Planetary health.

811 This perspective is global since Planetary Health needs to be tackled in all countries and the World Health
812 Organization and the International Telecommunication Union recognize the importance of mHealth
813 globally and particularly in developing countries (5).

814 **Value added medicines: the example of the combination of intra-nasal** 815 **antihistamine and corticosteroid used as needed**

816 Value added medicines represent the concept of drug repurposing (83). They are medicines based on
817 known molecules that address healthcare needs and deliver relevant improvement for patients, healthcare
818 professionals and/or payers. MASK is a proof-of-concept of drug repurposing as it suggests the importance
819 of as needed treatment for AR. Value added medicines are medicines based on known molecules that
820 address healthcare needs (8, 13, 18), deliver relevant improvement for patients (32, 33, 73, 84), health care
821 professionals (32, 33) and payers (29-31, 34). It contributes to addressing unmet patient needs, moving
822 from a tailored and patient's specific approach. By answering patients' unmet needs, they represent a new
823 horizon for those who are currently looking forward to a better quality of life with their treatment.

824 **Contribution of MASK to the EU Digital Single Market**

825 The Digital Single Market (<https://ec.europa.eu/digital-single-market/en>), part of the Digital Agenda for
826 Europe 2020 program of the EU includes three "pillars": (i) Access to online products and services, (ii)
827 conditions for digital networks and services and (iii) growth of the European digital economy. MASK is
828 involved in this strategy by (i) the management of care process, (ii) digital networks (ARIACARE-digital
829 network), (iii) innovation to market (I2M) to foster the cross- border adoption of digitally driven
830 marketable solutions, (iv) the political, organizational, technological and financial readiness, (v) the
831 contribution to European co-operation and transferability, (vi) and the contribution to the European Digital
832 Transformation of Health and Care (Bousquet et al., submitted).

833 The digital transformation of health and care can improve the quality of health services and ultimately
834 people's health and well-being as well as the economy in line with EIT Health. In the context of
835 implementing communication on the digital transformation of health and care, DG SANTE, in
836 collaboration with the EU Commission Expert Group "Steering Group on Health Promotion, Disease

837 Prevention and Management of Non-Communicable Diseases”
838 (<https://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=3622>),
839 scaled-up good practices in the field of digitally-enabled, integrated, person-centred care. MASK was one
840 of the nine Good Practices selected, along with chronic disease and Parkinson’s disease (14).

841 **Political agenda**

842 In the severe asthma TWINNING, the engagement through the Salerno local health agency of
843 ProMIS@Campania network (76) will ensure that adoption is progressively achieved through a
844 multicentric scale-up pilot. The good practice will then be scaled up to other Italian regions through the
845 National ProMIS network (85).

846 The EU political agenda is of great importance in supporting the digital transformation of health and care
847 for chronic respiratory diseases. The Polish Presidency of the EU Council (2011) prioritized the early
848 diagnosis, prevention and control of chronic respiratory diseases in children (86). AIRWAYS-ICPs
849 (Integrated care pathways for airway diseases) (7), initiated in 2014 by the EIP on AHA (6, 8), launched a
850 collaboration to develop multi-sectoral ICPs. It was a GARD (87) demonstration project (88).

851 Euforea (European Forum for Research and Education in Allergy and Airway Diseases) proposed a yearly
852 stepwise strategy at the EU or ministerial levels (89-91). Euforea organized an EU Summit in Vilnius,
853 Lithuania (March 2018) to propose multisectoral ICPs embedding guided self-management, mHealth and
854 air pollution in chronic respiratory diseases (92).

855 POLLAR (Impact of air POLLution on Asthma and Rhinitis, EIT Health) is focusing on the impact of
856 allergens and air pollution on airway diseases to propose novel ICPs integrating pollution, sleep and patient
857 literacy (21). Aquas, the Catalonia Health Agency is involved in POLLAR.

858 **Change management**

859 ARIA phase 4 focusses on Change Management with the aim of providing an active and healthy life to
860 rhinitis sufferers and to those with asthma multimorbidity across the life cycle - whatever their gender or
861 socio-economic status - in order to reduce health and social inequities incurred by the disease. ARIA has
862 followed the 8-step model of Kotter (93) to assess and implement the impact of rhinitis on asthma
863 multimorbidity and to propose multimorbid guidelines (12). A second change management strategy is
864 proposed by ARIA Phase 4 on the digital transformation of health and care.

865 **Conclusion: towards a revolution in rhinitis and asthma management**

866 The MASK strategy represents a proof-of-concept for other chronic diseases as asthma-rhinitis
867 multimorbidity plays a key role in understanding asthma and can be used as a general model of
868 multimorbidity. Moreover, asthma and rhinitis have a life-course approach whereas most chronic diseases
869 start early in life but are only clinically evident in adulthood. The lessons learnt by the MASK strategy are
870 therefore transposable to other chronic diseases.

871 Anamorphosis is a metaphor for reimagining and expanding on appearances and overcoming
872 otherness. MASK digital anamorphosis makes it possible to look at data from a different angle. The data
873 then appear to be different to their familiar, expected and/or generally-accepted form. Anamorphosis may
874 be associated with fear as phenomenological otherness often accompanies new technology. Education for a
875 better appraisal of mHealth by all stakeholders is therefore essential. Metaphorical language can facilitate
876 communication and shape of thought, thus providing key challenges and opportunities for future
877 research (105).

878 mHealth has the potential to profoundly impact healthcare (94). mHealth apps now represent an important
879 evolution of health and care for allergic rhinitis and asthma multimorbidity. The Digital revolution is
880 underway for rhinitis and asthma (5). Innovative health strategies and services will change management (6)
881 and create a new kind of partnership between the patients, the health care providers and the health system.

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Funding source

MASK funding was obtained from EU grants (SPAL, POLLAR, Sunfrail, Rhinitis and asthma Twinning, DHE Twinning on severe asthma), the Région Occitanie (France), unrestricted educational grants (Meda, Mylan, ALK, GSK, Novartis, Sanofi, Stallergènes and Uriach) and private donations. Euforea provided assistance for the ARIA website and the physician's questionnaire

Table 1: Strategic overview

	Acronym	Name	Dates
WHO-associated projects			
	ARIA	Allergic Rhinitis and its Impact on Asthma	1999-
		WHO collaborating Center on rhinitis and asthma	2004-14
	GARD	Global Alliance against Chronic Respiratory Diseases	2003-
EU grants and projects			
	GA ² LEN	Global Allergy and Asthma European Network (FP6)	2004-
	MeDALL	Mechanisms of the Development of Allergy (FP7)	2009-14
	Sunfrail		
	EIP on AHA	European Innovation Partnership on Active and Healthy Ageing (DG Santé & CONNECT)	2012-20
	Twinning	Transfer of Innovation	2017-9
	DHE Twinning	Transfer of innovation in severe asthma (H2020)	2019-20
	Vigour		2019-21
	POLLAR	Impact of Pollution on Asthma and Rhinitis (EIT health)	2018-9
		Good Practice DG Santé on digital health (DG Santé)	2018

ARIA: Allergic Rhinitis and its impact on Asthma, CARAT: Control of Allergic Rhinitis and Asthma Test, EAACI:

European Academy of Allergy and Clinical Immunology, e-CDSS: electronic clinical decision support system, GA²LEN:

Global Allergy and Asthma European Network, GARD: Global Alliance against Chronic Respiratory Diseases, POLLAR:

Impact of Pollution in Asthma and Rhinitis, WHO: World Health Organization

Table 2: Vision of MASK

- 1- The burden of rhinitis and asthma (multimorbidity) and unmet medical needs are unacceptable and require a novel approach to tackle them
- 2- Health care costs should be sustainable despite the increased prevalence of allergic diseases and the availability of new expensive treatments
- 3- mHealth should be applied to rhinitis and asthma to reduce unmet medical needs and sustain health care costs
- 4- A novel approach should embed medical knowledge, patient's needs and mHealth
- 5- The ultimate goal is change management for rhinitis and asthma

Table 3: Maturity level of MASK

MASK achievement	TRL	
App for rhinitis and mulitmorbidity (MASK-air®): available in 25 countries, 17 languages, 35,000 users	9	(18, 32, 72)
CARAT questionnaire for screening and control of rhinitis and asthma, available in 20 countries	9	(38-40)
e-physician questionnaire for rhinitis (available on the Euforea website) deployed in 23 countries and 17 languages	9	(16)
Embedding air quality (outdoor air pollution) and pollen data in MASK-air® (POLLAR)	9	(21)
e-CDSS for share decision making in rhinitis	7	(15)
EAACI-ARIACARE-digital network	8	
Allergy score	7	(28)
Embedding artificial intelligence in MASK-air®	3	

CARAT: Control of Allergic Rhinitis and Asthma Test, EAACI: European Academy of Allergy and Clinical Immunology, e-CDSS: electronic clinical decision support system, POLLAR: Impact of Pollution in Asthma and Rhinitis

Table 4: Patients' needs and expectations of an mHealth app

A- Problems patients encounter using an app

- Fear of using an App (in particular in elderly patients)
- Customer loyalty problems (young adult patients)
- Not willing to use one App regularly
- Changing the App frequently
- Not understanding how to fill in the App
- Not understanding or not caring about what must be done (e.g. seeing a physician), despite clear results/instructions provided by the App
- Not feeling ill (usually males)
- Feeling too ill and filling in the App too much (females, some males also)

B- Patients' expectations

Patients' expectations	Existing feature in MASK	To be added to MASK	
		Feature	Expected
Advice to modify the treatment	Simple advice exists in line with the GDPR		
		More sophisticated advice will be ready with Medical Device Regulation (MDR) Class 2A	06-2021*
Pollen and pollution		POLLAR	6-2020
Visualization of control and medications	Existing but poorly found by patients and physicians	More user friendly and better information	6-2020
Help science to better understand the disease in order to get future benefits	Existing		

GDPR: General Data Protection Regulation, MASK: Mobile Airway Sentinel Network, POLLAR: Impact of Pollution in Asthma and Rhinitis

*: due to new regulation not yet published

	assessment	<p>treatment or single treatment. These observations are in contradistinction with guidelines.</p> <ul style="list-style-type: none"> • Patients do not follow guidelines or the physician's prescriptions and self-medicate. Next-generation guidelines are needed. <p>Chamber studies confirm the speed of onset of some treatments</p>	turned to partnership using novel models of education (IT).	(73)
5	The same tool is used for RCTs, RWD, chamber studies and clinical practice	A symptom-medication score (SMS) based on MASK has been set up and can be used for all purposes.	<ul style="list-style-type: none"> • Assessment of SMS in RCTs, observational studies, chamber challenges and clinical practice. • Direct comparison of RCTs, observational studies, chamber challenges with RWD in patients. • Patient stratification for expensive treatments. 	
Health outcomes				
6	Health outcomes and impact	<ul style="list-style-type: none"> • There is a significant correlation between VAS work and VAS for global symptoms, nose, eye or asthma. <p>Daily VAS work can be used for economic studies.</p>	<ul style="list-style-type: none"> • Work productivity • EQ5D • Impact (sleep) 	(29-31, 34, 99)
Next-generation care pathways				
7	Next-generation care pathways	<ul style="list-style-type: none"> • Care pathways differ from guidelines. • Self-care. • Pharmacist • Physician • Patients 	<p>Next-generation care pathways are needed</p> <ul style="list-style-type: none"> • To account for real-world evidence • To provide a holistic view of management and prevention of allergic symptoms and diseases 	(55, 67, 68, 72, 100) (37)
8	Air pollution	<ul style="list-style-type: none"> • Air pollution impacts the severity of rhinitis. 	<ul style="list-style-type: none"> • Embedding in MASK-air® current data and 3-day 	(21, 36)

		<ul style="list-style-type: none"> Prediction of pollution and the pollen season (POLLAR) 	<p>prediction for pollen season and air quality.</p> <ul style="list-style-type: none"> Alerts for peaks of pollen and pollution. 	
Centres of excellence in digital health				
9	Centres of Excellence	ARIACARE-Digital is a novel network with the aim to implement the digital transformation of health and care in airway diseases	<ul style="list-style-type: none"> ARIACARE-Digital 	
Transfer of innovation				
10	Rhinitis-TWINNING	Completed (but still ongoing) TWINNING in rhinitis and asthma	<ul style="list-style-type: none"> Web-based physician's questionnaire MASK-air® combined 	(16, 76)
11	Asthma-TWINNING	DHE TWINNING in severe asthma	<ul style="list-style-type: none"> Asthma-e-platform MASK-air® with asthma combined ARIACARE-Digital 	
Digital transformation of health and care to sustain Planetary Health				
12	POLLAR	<ul style="list-style-type: none"> Impact of climate change, air pollution and biodiversity 	<ul style="list-style-type: none"> Climate change 	(21, 36)
13	Finland's EU Presidency meeting, December 3-4, 2019	<ul style="list-style-type: none"> Care pathways for rhinitis and/or asthma can be used as a model for all chronic diseases. 	<ul style="list-style-type: none"> The way to the digital transformation of health to sustain planetary health 	Bousquet et al, in preparation

A*: anamorphosis

CARAT: Control of Allergic Rhinitis and Asthma Test, DHE: DigitalHealthEurope, EQ5D: EuroQuol, MASK: Mobile Airway Sentinel network, RCT: Randomized Control Trial, RWD: Real World Data, Twinning: Transfer of Innovation, VAS: Visual analogue scale

Table 6: Papers of next-generation care pathways in the digital transformation of health and care

	Title	Journal	Publication
1	From ARIA guidelines to the digital transformation of health in rhinitis and asthma multimorbidity	Eur Respir J	(9)
2	Mobile technology in allergic rhinitis: evolution in management or revolution in health and care?	JACI Practice	(5)
3	Next-generation ARIA care pathways for rhinitis and asthma: a model for multimorbid chronic diseases	CTA	(79)
4	2018 Good Practice: ARIA digitally-enabled, integrated, person-centred care for rhinitis and asthma <i>Practice presented during the Steering Group on Promotion and Prevention marketplace workshop on "digitally-enabled, integrated, person-centred care" best practices on 12-13 December 2018 in the premises of the Joint Research Centre in Ispra, Italy</i>	CTA	(14)
5	Next-generation care pathways for allergic rhinitis and asthma multimorbidity: a model for multimorbid non-communicable diseases (Meeting Report. Part 1)	J Thorac Dis	(65)
6	Next-generation care pathways for allergic rhinitis and asthma multimorbidity: a model for multimorbid non-communicable diseases (Meeting Report. Part 2)	J Thorac Dis	(66)
7	ARIA pharmacy 2018: "Allergic rhinitis care pathways for community pharmacy"	Allergy	(67)
9	ARIA Care pathways for allergen-specific immunotherapy following the ARIA recommendations to fill gaps in knowledge (101)	Allergy	(68)
10	ARIA-EAACI Care pathways for allergen-specific immunotherapy Pocket Guide		
11	Next-generation ARIA guidelines for allergic rhinitis based on GRADE and real-world evidence, validating the management algorithm (54), following GRADE recommendations (69, 70, 102) and chamber studies (73, 103)	JACI	(79)
12	Digital transformation of health and care in asthma	Allergy	
13	2020 DHE Twinning on severe asthma		
14	Uniform stratification of severe chronic diseases in adults using		

	mobile technology: App-MM		
15	ARIA Phase 4 (2018): Change management in allergic rhinitis and asthma multimorbidity using mobile technology	JACI	(12)

App-MM: Appfor multimorbidity,ARIA: Allergic Rhinitis and its impact on Asthma, CARAT: Control of Allergic Rhinitis and Asthma Test, CTA: Clinical and Translational Allergy, DHE: DigitalHealthEurope, EAACI: European Academy of Allergy and Clinical Immunology, JACI: Journal of Allergy and Clinical Immunology, Twinning: Transfer of Innovation

Figure 1: Care pathways proposed in the MASK strategy (adapted from (6))

Figure 2: Next-generation ARIA care pathways

AIT: Allergen Immunotherapy

Conflict of interest

MA reports personal fees from POCI-01-0145-FEDER-029130 mINSPIRERS—mHealth to measure and improve adherence to medication in chronic obstructive respiratory diseases – generalisation and evaluation of gamification, peer support and advanced image processing technologies from ERDF (European Regional Development Fund) funded by the COMPETE2020 and by National Funds through FCT (Fundação para a Ciência e a Tecnologia). EB reports personal fees from Novartis, Menarini, ALK, Sanofi Regeneron, Boehringer Ingelheim, AstraZeneca, Sanofi Genzyme, Orion, and is a member of the Science Committee and Board of the Global Initiative for Asthma (GINA). PB reports personal fees and other from Roche, Boehringer, Novartis, personal fees from AstraZeneca, TEVA, other from Chiesi, Stallergenes. LPB reports Research grants for participation to multicentre studies from AstraZeneca, Boston Scientific, GlaxoSmithKline, Hoffman La Roche, Novartis, Ono Pharma, Sanofi, Takeda, Support for research projects introduced by the investigator from AstraZeneca, Boehringer-Ingelheim, GlaxoSmithKline, Merck, Takeda, Fee for consulting and advisory boards from Astra Zeneca, Novartis, Methapharm, nonprofit grants for production of educational materials from AstraZeneca, Boehringer-Ingelheim, GlaxoSmithKline, Merck, Novartis, conference fees from AstraZeneca, GlaxoSmithKline, Merck, Novartis, support for participation in conferences and meetings from Novartis, Takeda. JB reports personal fees from Chiesi, Cipla, Hikma, Menarini, Mundipharma, Mylan, Novartis, Purina, Sanofi-Aventis, Takeda, Teva, Uriach, other from KYomed-Innov.

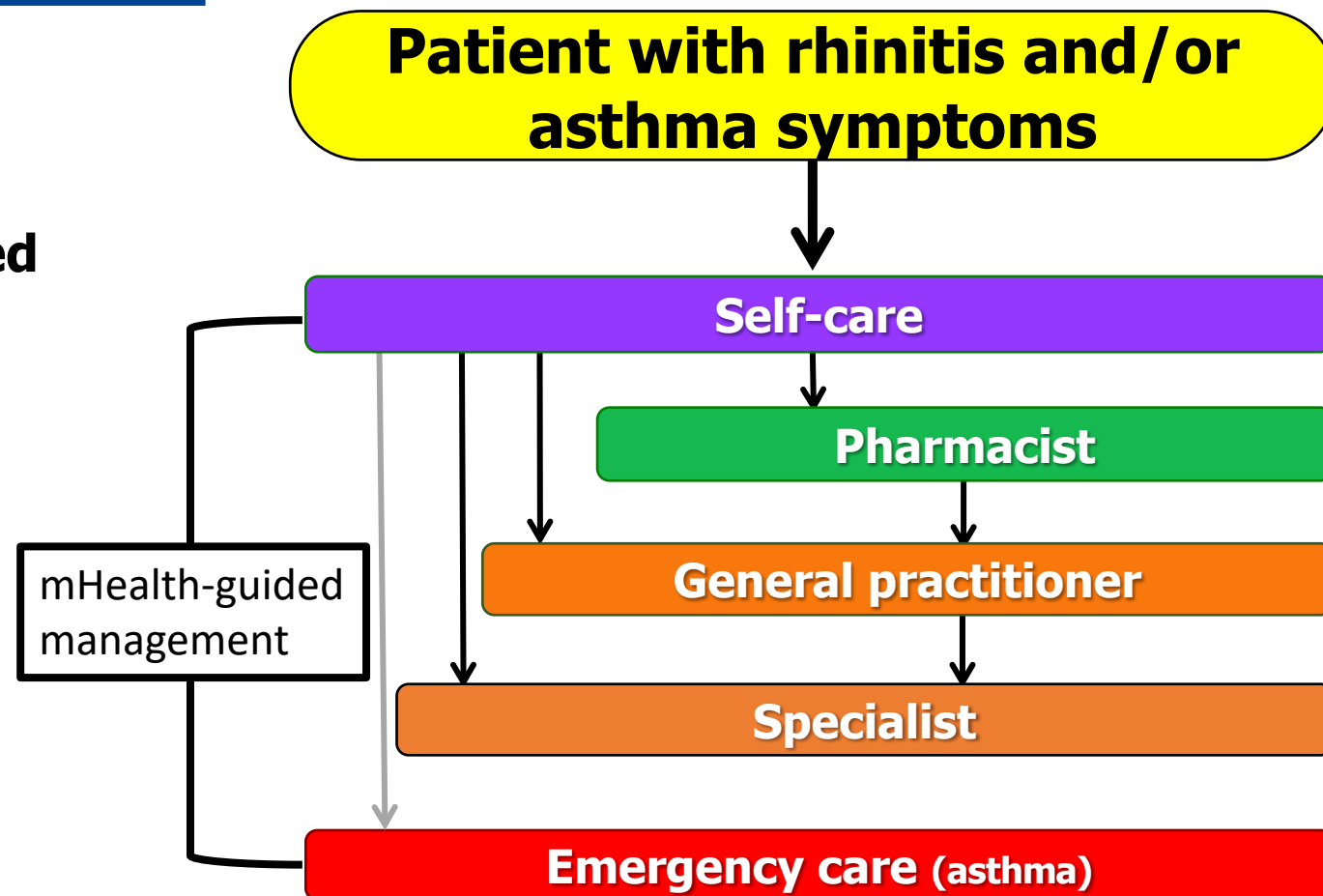
RB reports personal fees from AstraZeneca, Chiesi, Cipla, Sanofi and Teva, grants and personal fees from Boehringer Ingelheim, Novartis and Roche, and grants from GlaxoSmithKline, all outside the submitted work. VC reports personal fees from ALK, Allergopharma, Allergy Therapeutics, Diater, LETI, Thermofisher, Stallergenes. JCS reports other from Boehringer Ingelheim, GSK, personal fees, non-financial support and other from AstraZeneca, personal fees and other from Mundipharma. AC reports personal fees from Novartis, Regeneron, Thermo Fisher Scientific, Philips, Sanofi. ME reports personal fees from DBV Technologies, Mylan. JF reports being a partner in a company developing mobile technologies for monitoring airways diseases. EH reports personal fees from AstraZeneca, Novartis, GSK, Sanofi-Genzyme, Teva, Circassia, Nestlé Purina. GI is consultant for Amicus Therapeutics and received a research grant from Amicus therapeutics. PK reports personal fees from Aflofarm, Fresenius, Lek-AM, Novartis, Polpharma, Sandoz, grants from European Union, European Commission. LK reports personal fees from Allergopharma, HAL Allergie, ALK Abelló, LETI Pharma, Allergy Therapeut, Stallergenes, Quintiles, AstraZeneca, GSK, ASIT biotech, Lofarma, grants and personal fees from MEDA/Mylan, Sanofi. DLL reports personal fees from Amstrong, Astrazeneca, Boehringer Ingelheim, Chiesi, DBV Technologies, Grunenthal, GSK, MEDA, Menarini, MSD, Novartis, Pfizer, Novartis, Sanofi, Siegfried, UCB. grants from Sanofi, Astrazeneca, Novartis, UCB, GSK, TEVA, Boehringer Ingelheim, Chiesi. RL reports grants and personal fees from GSK, from AZ, Novartis, grants from Chiesi. Dr. Loureiro reports personal fees from Astra-Zeneca, Novartis, GSK, Sanofi, TEVA, Menarini. JM reports personal fees and non-financial support from NOVARTIS, SANOFI, ASTRA ZENECA, INMUNOTEK. MM reports grants and personal fees from Aralez, AstraZeneca, FAES, Genentech, Novartis, MSD, Roche, Sanofi, UCB, Uriach. JM

reports personal fees from ALK-Abelló, Sanofi-Genzyme & Regeneron, Menarini Group, MSD, Mitsubishi-Tanabe, Novartis, UCB Pharma, GENENTECH - Roche, grants and personal fees from URIACH Group, MYLAN-MEDA Pharma. AM reports personal fees from Aimmune, DVB, Nestlé Health Institute, Nestlé Purina. BN reports other from Co-founded AsthmaTuner, eHealth system for asthma. YO reports personal fees from Kyowa Co., Ltd, Eizai Co., Ltd, Shionogi Co., Ltd., Torii Co., Ltd., GSK, MSD, grants and personal fees from Kyorin Co., Ltd., Tiho Co., Ltd., grants from Yakuruto Co., Ltd., Yamada Bee Farm. NP reports personal fees from Novartis, Nutricia, HAL, MENARINI/FAES FARMA, SANOFI, MYLAN/MEDA, BIOMAY, AstraZeneca, GSK, MSD, ASIT BIOTECH, Boehringer Ingelheim, grants from Gerolymatos International SA, Capricare. JLP reports grants and personal fees from Air Liquide Foundation, Agiradom, AstraZeneca, Philips, Resmed, grants from Fisher and Paykel, Mutualia, Vitalaire, personal fees from Boehringer Ingelheim, Jazz pharmaceutical, Night Balance, Sefam. DP reports personal fees, non-financial support and other from Revenio, grants and personal fees from GlaxoSmithKline, personal fees from Merck, Sandoz, other from Boehringer Ingelheim, Novartis, MSD, Chiesi, non-financial support from Menarini, non-financial support from Pharmas, personal fees and non-financial support from Salveo. DP reports personal fees from Amgen, Mundipharma, Novartis, Pfizer, Regeneron Pharmaceuticals, Cipla, GlaxoSmithKline, Kyorin, Thermofisher, grants and personal fees from AstraZeneca, Behringer Ingelheim, Chiesi, Circassia, Mylan, grants from Respiratory Effectiveness Group, Sanofi Genzyme, Teva, Theravance, grants from UK National Health Service, non-financial support from Efficacy and Evaluation Mechanism Programme, Health Technology Assessment and stock/stock options from AKL Research and Development Ltd which produces phytopharmaceuticals; and owns 74% of the social enterprise Optimum Patient Care Ltd (Australia and UK) and 74% of Observational and Pragmatic Research Institute Pte Ltd (Singapore). FP has been scientific consultant, researcher, speaker supported by the following commercial companies: Menarini, Alk-Abello, Almirall, Allergy Therapeutics, Anallergo, AstraZeneca, Boehringer Ingelheim, Chiesi Farmaceutici, GSK, Hal Allerg, Lab.Guidotti, Lofarma, Malesci, MSD, Mundifarma, Novartis, Roche, Sanofi, Stallergenes, Valea. Dr Sastre is consultant for Thermofisher, Hycor, Novartis, Sanofi, Leti, Mundipharma, ALK, GSK. Payed conferences from Novartis, GSK, Circassia, Sanofi, LETI, FAES FARMA. Research grants from Thermofisher, Mundipharma, ALK, Sanofi. GS reports personal fees from ALK, Mylan, ALK, other from Rhinology & Laryngology Research Fund, BSACI, EAACI. MS reports fees from ASIT Biotech.sa, ALK, Allergopharma. AMTB reports grants and personal fees from Novartis, Sanofi, Mundipharma, GSK (GlaxoSmithKline), Teva Pharma, personal fees from AstraZeneca, grants from Boehringer Ingelheim, outside the submitted work. IT reports personal fees from Honoraria for educational activities, speaking engagements, advisory boards from Boehringer Ingelheim, Astra Zeneca, GSK, Novartis and grants from GSK Hellas and Elpen. MW reports personal fees from ALK-Abello, AstraZeneca, Bencard Allergie, HAL Allergy, Leti Pharma, Meda Pharma, Novartis, Sanofi Aventis, Stallergenes, Teva. SWreports personal fees and other from CSL Behring, Shire, AstraZeneca, Teva, Meda, Merck, GSK, Novartis, personal fees from Pediapharm, Aralez, Sanofi, Stallergenes. The other authors have no COI to declare.

Transformation of Health and Care in the Digital Single Market

Chapter 5

“Digital tools for citizen empowerment and for person-centred care”



Differences exist between countries/regions and health care systems

