

## REVIEW

# ARIA-EAACI care pathways for allergen immunotherapy in respiratory allergy

Jean Bousquet<sup>1,2,3</sup>  | Oliver Pfaar<sup>4</sup> | Ioana Agache<sup>5</sup> | Anna Bedbrook<sup>3</sup> | Cezmi A Akdis<sup>6</sup> | G. Walter Canonica<sup>7,174</sup> | Tomas Chivato<sup>8</sup> | Mona Al-Ahmad<sup>9,175</sup> | Amir H Abdul Latiff<sup>10</sup> | Ignacio J Ansotegui<sup>11</sup> | Claus Bachert<sup>12,176,177</sup> | Abdullah Baharuddin<sup>13</sup> | Karl-Christian Bergmann<sup>1</sup> | Carsten Bindslev-Jensen<sup>14,177,178</sup> | Leif Bjermer<sup>15</sup> | Matteo Bonini<sup>16,179</sup> | Sinthia Bosnic-Anticevich<sup>17,180</sup> | Isabelle Bosse<sup>18</sup> | Helen A. Brough<sup>19</sup> | Luisa Brussino<sup>20</sup> | Moises A Calderon<sup>21</sup> | Luis Caraballo<sup>22,181</sup> | Victoria Cardona<sup>23</sup>  | Pedro Carreiro-Martins<sup>24,182</sup> | Tomas Casale<sup>25</sup> | Lorenzo Cecchi<sup>26</sup> | Alfonso M Cepeda Sarabia<sup>27,183</sup> | Ekaterine Chkhartishvili<sup>28</sup> | Derek K Chu<sup>29</sup> | Ieva Cirule<sup>30</sup> | Alvaro A Cruz<sup>31</sup> | Wienczyslawa Czarlewski<sup>32</sup> | Stefano del Giacco<sup>33</sup> | Pascal Demoly<sup>34,184</sup> | Philippe Devillier<sup>35</sup> | Dejan Dokic<sup>36</sup> | Stephen L Durham<sup>37</sup> | Motohiro Ebisawa<sup>38</sup> | Yehia El-Gamalt<sup>39</sup> | Regina Emuzyte<sup>40</sup> | Amiran Gamkrelidze<sup>41</sup> | Jean Luc Fauquet<sup>42</sup> | Alessandro Fiocchi<sup>43</sup> | Wytske J Fokkens<sup>44,185</sup> | Joao A Fonseca<sup>45,186</sup> | Jean-François Fontaine<sup>46</sup> | Radoslaw Gawlik<sup>47</sup> | Asli Gelincik<sup>48</sup> | Bilun Gemicioglu<sup>49</sup> | Jose E Gereda<sup>50</sup> | Roy Gerth van Wijk<sup>51</sup> | R Maximiliano Gomez<sup>52</sup> | Maia Gotua<sup>53</sup> | Ineta Grisle<sup>54</sup> | Maria-Antonieta Guzmán<sup>55</sup> | Tari Haahtela<sup>56</sup> | Susanne Halken<sup>57</sup> | Enrico Heffler<sup>7</sup> | Karin Hoffmann-Sommergruber<sup>58</sup> | Elham Hossny<sup>59</sup> | Martin Hrušičko<sup>60</sup> | Carla Irani<sup>61</sup> | Juan Carlos Ivancevich<sup>62</sup> | Zhanat Ispayeva<sup>63</sup> | Kaja Julge<sup>64</sup> | Igor Kaidashev<sup>65</sup> | Omer Kalayci<sup>66</sup> | Musa Khaitov<sup>67</sup> | Ludger Klimek<sup>68,187</sup> | Edward Knol<sup>69</sup> | Marek L Kowalski<sup>70</sup> | Helga Kraxner<sup>71</sup> | Inger Kull<sup>72,188</sup> | Piotr Kuna<sup>73</sup> | Violeta Kvedariene<sup>74,189</sup> | Vicky Kritikos<sup>75,190</sup> | Antti Lauerma<sup>76</sup> | Susanne Lau<sup>77</sup> | Daniel Laune<sup>78</sup> | Michael Levin<sup>79</sup> | Desiree E Larenas-Linnemann<sup>80</sup> | Karin C Lodrup Carlsen<sup>81,191</sup> | Carlo Lombardi<sup>82</sup> | Olga M Lourenço<sup>83</sup> | Bassam Mahboub<sup>84</sup> | Hans-Jørgen Malling<sup>85</sup> | Patrick Manning<sup>86</sup> | Gailen D Marshall<sup>87</sup> | Erik Melén<sup>88,188</sup> | Eli O Meltzer<sup>89</sup> | Neven Miculinic<sup>90</sup> | Branislava Milenkovic<sup>91,193</sup> | Mostafa Moin<sup>92</sup> |

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Stephen Montefort<sup>93</sup> | Mario Morais-Almeida<sup>94</sup> | Charlotte G Mortz<sup>14</sup> |  
 Ralph Mösge<sup>95</sup>  | Joaquim Mullo<sup>96,194</sup> | Leyla Namazova Baranova<sup>97</sup> |  
 Hugo Neffen<sup>98</sup> | Kristof Nekam<sup>99</sup> | Marek Niedozytko<sup>100</sup> | Mikaëla Odemyr<sup>101</sup> |  
 Robyn E O'Hehir<sup>102,195</sup> | Markus Ollert<sup>103,196</sup> | Liam O'Mahony<sup>104</sup> | Ken Ohta<sup>105</sup> |  
 Yoshitaka Okamoto<sup>106</sup> | Kimi Okubo<sup>107</sup> | Giovanni B Pajno<sup>108</sup> |  
 Oscar Palomares<sup>109</sup> | Susanna Palkonen<sup>110</sup> | Petr Panzner<sup>110</sup> |  
 Nikolaos G Papadopoulos<sup>111</sup> | Hae-Sim Park<sup>112</sup> | Giovanni Passalacqua<sup>113</sup> |  
 Vincenzo Patella<sup>114</sup> | Ruby Pawankar<sup>115</sup> | Nhat Pham-Thi<sup>116</sup> | Davor Plavec<sup>117</sup> |  
 Todor A Popov<sup>118</sup> | Marysia Recto<sup>192</sup> | Frederico S Regateiro<sup>119,197,198</sup> |  
 Carmen Riggioni<sup>120,199</sup> | Graham Roberts<sup>121</sup> | Monica Rodriguez-Gonzales<sup>122</sup> |  
 Nelson Rosario<sup>123</sup> | Menachem Rottem<sup>124,200</sup> | Philip W Rouadi<sup>125</sup> |  
 Dermot Ryan<sup>126</sup>  | Boleslaw Samolinski<sup>127</sup> | Mario Sanchez-Borgest<sup>128</sup> |  
 Faradiba S Serpa<sup>129</sup> | Joaquin Sastre<sup>130</sup> | Glenis K. Scadding<sup>131</sup> |  
 Mohamed H Shamji<sup>132,201</sup> | Peter Schmid-Grendelmeier<sup>133</sup> | Holger J Schünemann<sup>29</sup> |  
 Aziz Sheikh<sup>134</sup> | Nicola Scichilone<sup>135</sup> | Juan Carlos Sisul<sup>136</sup> | Mikhail Sofiev<sup>137</sup> |  
 Dirceu Solé<sup>138</sup> | Talant Sooronbaev<sup>139</sup> | Manuel Soto-Martinez<sup>140</sup> |  
 Manuel Soto-Quiros<sup>141</sup>  | Milan Sova<sup>142</sup> | Jürgen Schwarze<sup>143</sup> |  
 Isabel Skypala<sup>144</sup>  | Charlotte Suppli-Ulrik<sup>145,202</sup> | Luis Taborda-Barata<sup>146,203</sup> |  
 Ana Todo-Bom<sup>147,204</sup> | Maria J Torres<sup>148</sup> | Marilyn Valentin-Rostan<sup>149</sup> |  
 Peter-Valentin Tomazic<sup>150</sup> | Antonio Valero<sup>151</sup> | Sanna Toppila-Salmi<sup>56</sup> |  
 Ioanna Tsiligianni<sup>152,172</sup> | Eva Untersmayr<sup>153</sup> | Marilyn Urrutia-Pereira<sup>154</sup> |  
 Arunas Valiulis<sup>155,173</sup> | Erkka Valovirta<sup>156,205</sup> | Olivier Vandenplas<sup>157</sup> |  
 Maria Teresa Ventura<sup>158</sup> | Pakit Vichyanond<sup>159</sup> | Martin Wagenmann<sup>160</sup> |  
 Dana Wallace<sup>161</sup> | Jolanta Walusiak-Skorupa<sup>162</sup> | De Yun Wang<sup>163</sup> |  
 Susan Wasserman<sup>164</sup> | Gary WK Wong<sup>165</sup> | Arzu Yorgancioglu<sup>166</sup> |  
 Osman M Yusuf<sup>167</sup> | Mario Zernotti<sup>168</sup> | Luo Zhang<sup>169,206</sup> | Mihaela Zidarn<sup>170</sup>  |  
 Torsten Zuberbier<sup>1</sup> | Marek Jutel<sup>171,207</sup>

<sup>1</sup>Department of Dermatology and Allergy, Comprehensive Allergy Center, Charité Universitätsmedizin Berlin, Humboldt-Universität zu Berlin, and Berlin Institute of Health, Berlin, Germany

<sup>2</sup>Allergology, University Hospital Montpellier, Montpellier, France

<sup>3</sup>MACVIA-France, Montpellier, France

<sup>4</sup>Department of Otorhinolaryngology, Head and Neck Surgery Section of Rhinology and Allergy, University Hospital Marburg, Philipps-Universität Marburg, Germany

<sup>5</sup>Allergy and Clinical Immunology, Transylvania University Brasov, Brasov, Romania

<sup>6</sup>Swiss Institute of Allergy and Asthma Research (SIAF), University of Zurich, Davos, Switzerland

<sup>7</sup>Department of Biomedical Sciences, Humanitas University, Pieve Emanuele, (MI) and Personalized Medicine, Asthma and Allergy, Humanitas Clinical and Research Center IRCCS, Milano, Italy

<sup>8</sup>School of Medicine, University CEU San Pablo, Madrid, Spain

<sup>9</sup>Department of Allergy and Microbiology, Faculty of Medicine, Al-Rashed Allergy Center, Kuwait University, Kuwait City, Kuwait

<sup>10</sup>Allergy & Immunology Centre, Pantai Hospital Kuala Lumpur, Malaysia

<sup>11</sup>Department of Allergy and Immunology, Hospital Quironsalud Bizkaia, Erandio, Spain

<sup>12</sup>ENT Department, Upper Airways Research Laboratory, Ghent University Hospital, Ghent, Belgium

<sup>13</sup>Department of Otorhinolaryngology—Head and Neck Surgery, School of Medical Sciences, Universiti Sains Malaysia, Kubang Kerian, Kelantan, Malaysia

<sup>14</sup>Department of Dermatology and Allergy Centre, Odense University Hospital, Odense, Denmark

<sup>15</sup>Department of Respiratory Medicine and Allergology, University Hospital, Lund, Sweden

<sup>16</sup>Department of Cardiovascular and Thoracic Sciences, Fondazione Policlinico Universitario A Gemelli IRCCS, Università Cattolica del Sacro Cuore, Rome, Italy

<sup>17</sup>Woolcock Institute of Medical Research, University of Sydney, Australia

- <sup>18</sup>Allergist, La Rochelle, France
- <sup>19</sup>Paediatric Allergy, Department of Asthma, Allergy and Respiratory Science, Guys' Hospital, King's College London, London, UK
- <sup>20</sup>Department of Medical Sciences, Allergy and Clinical Immunology Unit, University of Torino & Mauriziano Hospital, Torino, Italy
- <sup>21</sup>Imperial College and National Heart and Lung Institute, London, UK
- <sup>22</sup>Institute for Immunological Research, University of Cartagena, Cartagena, Colombia
- <sup>23</sup>Allergy Section, Department of Internal Medicine, Hospital Vall d'Hebron & ARADyAL Research Network, Barcelona, Spain
- <sup>24</sup>Serviço de Imunoalergologia, Hospital de Dona Estefânia, Centro Hospitalar de Lisboa Central, Lisbon, Portugal
- <sup>25</sup>Division of Allergy/immunology, University of South Florida, Tampa, Fla, USA
- <sup>26</sup>SOS Allergology and Clinical Immunology, USL Toscana Centro, Prato, Italy
- <sup>27</sup>Allergy and Immunology Laboratory, Metropolitan University, Simon Bolivar University, Barranquilla, Colombia
- <sup>28</sup>David Tatishvili Medical Center, David Tvildiani Medical University-AIETI Medical School, Tbilisi, Georgia
- <sup>29</sup>Departments of Medicine and Health Research Methods, McMaster University, Hamilton, ON, Canada
- <sup>30</sup>Latvian Association of Allergists, University Children Hospital, Riga, Latvia
- <sup>31</sup>Fundação ProAR, Federal University of Bahia and GARD/WHO Planning Group, Salvador, Brazil
- <sup>32</sup>Medical Consulting Czarlewski, Levallois, France
- <sup>33</sup>Department of Medical Sciences and Public Health and Unit of Allergy and Clinical Immunology, University Hospital "Duilio Casula", University of Cagliari, Cagliari, Italy
- <sup>34</sup>Department of Pulmonology, Division of Allergy, Hôpital Arnaud de Villeneuve, University Hospital of Montpellier, France
- <sup>35</sup>Unité de Recherche en Pharmacologie Respiratoire, Pôle des Maladies des Voies Respiratoires, Hôpital Foch, Université Paris Saclay, Suresnes, France
- <sup>36</sup>Medical Faculty, University Clinic of Pulmology and Allergy, Skopje, Republic of Macedonia
- <sup>37</sup>National Heart and Lung Institute, Imperial College London, UK
- <sup>38</sup>Clinical Reserch Center for Allergy and Rheumatology, NHO Sagamihara National Hospital, Sagamihara, Japan
- <sup>39</sup>Pediatric Allergy and Immunology Unit, Children's Hospital, Ain Shams University, Cairo, Egypt
- <sup>40</sup>Faculty of Medicine, Clinic of Children's Diseases, Vilnius University, Vilnius, Lithuania
- <sup>41</sup>National Center for Disease Control and Public Health of Georgia, Tbilisi, Georgia
- <sup>42</sup>CHU Clermont-Ferrand, Unité d'Allergologie de l'Enfant, Pole pédiatrique, Hopital Estaing, Clermont-Ferrand, France
- <sup>43</sup>Division of Allergy, The Bambino Gesù Children's Hospital IRCCS, Rome, Italy
- <sup>44</sup>Department of Otorhinolaryngology, Academic Medical Centers, Amsterdam, The Netherland
- <sup>45</sup>Faculdade de Medicina, CINTESIS, Center for Health Technology and Services Research, Universidade do Porto, Porto, Portugal
- <sup>46</sup>Allergist, Reims, France
- <sup>47</sup>Department of Internal Medicine, Allergology and Clinical Immunology, Silesian University of Medicine, Katowice, Poland
- <sup>48</sup>Division of Allergy and Immunology, Dışkapı Yıldırım Beyazıt Training and Research Hospital, Ankara, Turkey
- <sup>49</sup>Department of Pulmonary Diseases, Cerrahpasa Faculty of Medicine, Istanbul University-Cerrahpasa, Istanbul, Turkey
- <sup>50</sup>Allergy and Immunology Division, Clínica Ricardo Palma, Lima, Peru
- <sup>51</sup>Department of Internal Medicine, Section of Allergology, Erasmus MC, Rotterdam, the Netherlands
- <sup>52</sup>Fundacion Ayre, Instituto Medico Alas, Salta, Argentina
- <sup>53</sup>Center of Allergy and Immunology, Georgian Association of Allergology and Clinical Immunology, Tbilisi, Georgia
- <sup>54</sup>Latvian Association of Allergists, Center of Tuberculosis and Lung Diseases, Riga, Latvia
- <sup>55</sup>Immunology and Allergy Division, Clinical Hospital, University of Chile, Santiago, Chile
- <sup>56</sup>Skin and Allergy Hospital, Helsinki University Hospital, Helsinki, Finland
- <sup>57</sup>Hans Christian Andersen Children's Hospital, Odense University Hospital, Odense, Denmark
- <sup>58</sup>Department of Pathophysiology and Allergy Research, Medical University of Vienna, Vienna, Austria
- <sup>59</sup>Pediatric Allergy and Immunology Unit, Children's Hospital, Ain Shams University, Cairo, Egypt
- <sup>60</sup>Department of Clinical Immunology and Allergy, Oncology Institute of St Elisabeth, Bratislava, Slovakia
- <sup>61</sup>Department of Internal Medicine and Infectious Diseases, St Joseph University, Hotel Dieu de France Hospital, Beirut, Lebanon
- <sup>62</sup>Servicio de Alergia e Immunologia, Clínica Santa Isabel, Buenos Aires, Argentina
- <sup>63</sup>Department of Allergology and Clinical Immunology of the Kazakh National Medical University, Kazakhstan Association of Allergology and Clinical Immunology, Kazakhstan
- <sup>64</sup>Allergy Center of Childrens's Clinic of Tartu University Hospital, Tartu, Estonia
- <sup>65</sup>Ukrainina Medical Stomatological Academy, Poltava, Ukraine
- <sup>66</sup>Pediatric Allergy and Asthma Unit, Hacettepe University School of Medicine, Ankara, Turkey
- <sup>67</sup>National Research Center, Institute of Immunology, Federal Medicobiological Agency, Laboratory of Molecular Immunology, Russia
- <sup>68</sup>Department of Otolaryngology, Head and Neck Surgery, Universitätsmedizin Mainz, Mainz, Germany
- <sup>69</sup>Departments of Immunology and Dermatology/Allergology, University Medical Center Utrecht, The Netherlands
- <sup>70</sup>Department of Immunology and Allergy, Healthy Ageing Research Center, Medical University of Lodz, Poland
- <sup>71</sup>Department of Otorhinolaryngology, Head and Neck Surgery, Semmelweis University, Budapest, Hungary
- <sup>72</sup>Department of Clinical Science and Education, Södersjukhuset, Karolinska Institutet, Stockholm, Sweden
- <sup>73</sup>Division of Internal Medicine, Asthma and Allergy, Barlicki University Hospital, Medical University of Lodz, Poland
- <sup>74</sup>Department of Pathology, Faculty of Medicine, Institute of Biomedical Sciences, Vilnius University Vilnius, Lithuania
- <sup>75</sup>Quality Use of Respiratory Medicines Group, Woolcock Institute of Medical Research, University of Sydney, Sydney, NSW, Australia
- <sup>76</sup>Department of Dermatology and Allergology, University of Helsinki and Helsinki University, Helsinki, Finland
- <sup>77</sup>Department of Pediatric Pneumology and Immunology, Charité Universitätsmedizin, Berlin, Germany
- <sup>78</sup>Yomed INNOV, Montpellier, France
- <sup>79</sup>Division of Paediatric Allergology, University of Cape Town, Cape Town, South Africa
- <sup>80</sup>Center of Excellence in Asthma and Allergy, Médica Sur Clinical Foundation and Hospital, México City, Mexico
- <sup>81</sup>Department of Paediatrics, Oslo University Hospital, Oslo, Norway
- <sup>82</sup>Departmental Unit of Allergology & Respiratory Diseases, Fondazione Poliambulanza, Brescia, Italy

- <sup>83</sup>Faculty of Health Sciences and CICS – UBI, Health Sciences Research Centre, University of Beira Interior, Covilhã, Portugal
- <sup>84</sup>Department of Pulmonary Medicine, Rashid Hospital, Dubai, UAE
- <sup>85</sup>Danish Allergy Centre, University of Copenhagen, Copenhagen, Denmark
- <sup>86</sup>Department of Medicine (RCSI), Bon Secours Hospital, Dublin, Ireland
- <sup>87</sup>The University of Mississippi Medical Center, Division of Clinical Immunology and Allergy, Laboratory of Behavioral Immunology Research, Jackson, Mississippi, USA
- <sup>88</sup>Sachs' Children and Youth Hospital, Södersjukhuset, Stockholm, Sweden
- <sup>89</sup>Allergy, Allergy and Asthma Medical Group and Research Center, San Diego, California, USA
- <sup>90</sup>Croatian Pulmonary Society, Zagreb, Croatia
- <sup>91</sup>Faculty of Medicine, Clinic for Pulmonary Diseases, Clinical Center of Serbia, University of Belgrade, Belgrade, Serbia
- <sup>92</sup>Immunology and Asthma and Allergy Research Institute, Tehran University of Medical Sciences, Tehran, Iran
- <sup>93</sup>Faculty of Medicine and Surgery, Mater Dei Hospital Malta, University of Medicine, La Valette, Malta
- <sup>94</sup>Allergy Center, CUF Descobertas Hospital, Lisbon, Portugal
- <sup>95</sup>CRI-Clinical Research International-Ltd, Hamburg, Germany
- <sup>96</sup>ENT Department, Rhinology Unit & Smell Clinic, Hospital Clínic, Barcelona, Spain
- <sup>97</sup>Scientific Centre of Children's Health, Russian National Research Medical University, Moscow, Russia
- <sup>98</sup>Center of Allergy, Immunology and Respiratory Diseases, Santa Fe, Argentina
- <sup>99</sup>Hospital of the Hospitaller Brothers in Buda, Budapest, Hungary
- <sup>100</sup>Department of Allergology, Medical University of Gdańsk, Gdańsk, Poland
- <sup>101</sup>EFA, European Federation of Allergy and Airways Diseases Patients' Associations, Brussels, Belgium
- <sup>102</sup>Department of Allergy, Immunology and Respiratory Medicine, Central Clinical School, Monash University, Victoria, Australia
- <sup>103</sup>Department of Infection and Immunity, Luxembourg Institute of Health, Esch-sur-Alzette, Luxembourg
- <sup>104</sup>Departments of Medicine and Microbiology, APC Microbiome Ireland, University College Cork, Cork, Ireland
- <sup>105</sup>National Hospital Organization, Tokyo National Hospital, Tokyo, Japan
- <sup>106</sup>Department of Otorhinolaryngology, Chiba University Hospital, Chiba, Japan
- <sup>107</sup>Department of Otolaryngology, Nippon Medical School, Tokyo, Japan
- <sup>108</sup>Department of Pediatrics, Allergy Unit, University of Messina, Messina, Italy
- <sup>109</sup>Department of Biochemistry and Molecular Biology, School of Chemistry, Complutense University of Madrid, Madrid, Spain
- <sup>110</sup>Department of Immunology and Allergology, Faculty of Medicine and Faculty Hospital in Pilsen, Charles University in Prague, Pilsen, Czech Republic
- <sup>111</sup>Division of Infection, Immunity & Respiratory Medicine, Royal Manchester Children's Hospital, University of Manchester, Manchester, UK
- <sup>112</sup>Department of Allergy and Clinical Immunology, Ajou University School of Medicine, Suwon, South Korea
- <sup>113</sup>Allergy and Respiratory Diseases, Ospedale Policlinico San Martino -University of Genoa, Italy
- <sup>114</sup>Department of Medicine, Division of Allergy and Clinical Immunology, Agency of Health ASL Salerno, "Santa Maria della Speranza" Hospital, Battipaglia, Salerno, Italy
- <sup>115</sup>Department of Pediatrics, Nippon Medical School, Tokyo, Japan
- <sup>116</sup>Ecole Polytechnique Palaiseau, IRBA (Institut de Recherche bio-Médicale des Armées), Bretigny, France
- <sup>117</sup>School of Medicine, Children's Hospital Srebrnjak, Zagreb, University J.J. Strossmayer, Osijek, Croatia
- <sup>118</sup>University Hospital 'Sv Ivan Rilski', Sofia, Bulgaria
- <sup>119</sup>Allergy and Clinical Immunology Unit, Centro Hospitalar e Universitário de Coimbra, Coimbra, Coimbra, Portugal
- <sup>120</sup>Pediatric Allergy and Clinical Immunology Department, Hospital Sant Joan de Déu, Barcelona, Spain
- <sup>121</sup>Salford Royal NHS Foundation Trust NHS England North, Salford, UK
- <sup>122</sup>Pediatric Allergy and Clinical Immunology, Hospital Angeles Pedregal, Mexico City, Mexico
- <sup>123</sup>Hospital de Clinicas, University of Parana, Brazil
- <sup>124</sup>Division of Allergy Asthma and Clinical Immunology, Emek Medical Center, Afula, Israel
- <sup>125</sup>Department of Otolaryngology-Head and Neck Surgery, Eye and Ear University Hospital, Beirut, Lebanon
- <sup>126</sup>Usher Institute, Medical School, University of Edinburgh, Edinburgh, UK
- <sup>127</sup>Department of Prevention of Environmental Hazards, Allergology and Immunology, Medical University of Warsaw, Warsaw, Poland
- <sup>128</sup>Allergy and Clinical Immunology Department, Centro Medico-Docente La Trinidad, Caracas, Venezuela
- <sup>129</sup>Asthma Reference Center - Escola Superior de Ciências, Santa Casa de Misericórdia of Vitória-Espírito Santo, Vitoria, Brazil
- <sup>130</sup>Faculty of Medicine, Fundacion Jimenez Diaz, CIBERES, Autonoma University of Madrid, Spain
- <sup>131</sup>The Royal National ENT Hospital, University College London, UK
- <sup>132</sup>Immunomodulation and Tolerance Group, Imperial College London, London, UK
- <sup>133</sup>Department of Dermatology, Allergy Unit, University Hospital of Zurich, Zürich, Switzerland
- <sup>134</sup>The Usher Institute of Population Health Sciences and Informatics, The University of Edinburgh, Edinburgh, UK
- <sup>135</sup>PROMISE Department, University of Palermo, Palermo, Italy
- <sup>136</sup>Sociedad Paraguaya de Alergia Asma e Inmunologia, Clinica Sisul, Allergy & Asthma, Asuncion, Paraguay
- <sup>137</sup>Finnish Meteorological Institute (FMI), Helsinki, Finland
- <sup>138</sup>Department of Pediatrics, Division of Allergy, Clinical Immunology and Rheumatology, Federal University of São Paulo, São Paulo, Brazil
- <sup>139</sup>Kyrgyzstan National Centre of Cardiology and Internal Medicine, Euro-Asian Respiratory Society, Bishkek, Kyrgyzstan
- <sup>140</sup>Department of Pediatrics, Division of Respiratory Medicine, Hospital Nacional de Niños, Universidad de Costa Rica, San Jose, Costa Rica
- <sup>141</sup>Department of Pediatrics, Hospital Nacional de Niños, San José, Costa Rica
- <sup>142</sup>Department of Respiratory Medicine, University Hospital Olomouc, Czech Republic
- <sup>143</sup>Centre for Inflammation Research, Child Life and Health, The University of Edinburgh, Edinburgh, UK
- <sup>144</sup>Royal Brompton and Harefield NHS Foundation Trust, London, UK
- <sup>145</sup>Department of Respiratory Medicine, Copenhagen University Hospital Hvidovre, Copenhagen, Denmark
- <sup>146</sup>Department of Immunoallergology, Faculty of Health Sciences, Cova da Beira, Covilhã, Portugal
- <sup>147</sup>Imunoalergologia, Centro Hospitalar Universitário de Coimbra, Coimbra, Portugal
- <sup>148</sup>Allergy Unit, Málaga Regional University Hospital-IBIMA, Málaga, Spain
- <sup>149</sup>Allergist, Montevideo, Uruguay
- <sup>150</sup>Department of General ORL, H&NS, ENT-University Hospital Graz, Medical University of Graz, Graz, Austria
- <sup>151</sup>Pneumology and Allergy Department, CIBERES, Clinical & Experimental Respiratory Immunoallergy, IDIBAPS, University of Barcelona, Barcelona, Spain
- <sup>152</sup>Department of Social Medicine, Health Planning Unit, Faculty of Medicine, University of Crete, Crete, Greece

- <sup>153</sup>Institute of Pathophysiology and Allergy Research, Center of Pathophysiology, Infectiology and Immunology, Medical University of Vienna, Vienna, Austria
- <sup>154</sup>Universidade Federal dos Pampa, Uruguai, Brazil
- <sup>155</sup>Faculty of Medicine, Vilnius University, Institute of Clinical Medicine & Institute of Health Sciences, Vilnius, Lithuania
- <sup>156</sup>Department of Lung Diseases and Clinical Immunology, University of Turku, Turku, Finland
- <sup>157</sup>Department of Chest Medicine, Centre Hospitalier Universitaire UCL Namur, Université Catholique de Louvain, Yvoir, Belgium
- <sup>158</sup>Unit of Geriatric Immunoallergy, University of Bari Medical School, Bari, Italy
- <sup>159</sup>Division of Allergy and Immunology, Department of Pediatrics, Faculty of Medicine, Siriraj Hospital, Mahidol University, Bangkok, Thailand
- <sup>160</sup>Department of Otorhinolaryngology, HNO-Klinik, Universitätsklinikum Düsseldorf, Germany
- <sup>161</sup>Nova Southeastern University, Fort Lauderdale, Florida, USA
- <sup>162</sup>Department of Occupational Diseases and Environmental Health, Nofer Institute of Occupational Medicine, Lodz, Poland
- <sup>163</sup>Department of Otolaryngology, Yong Loo Lin School of Medicine, National University of Singapore, Singapore, Singapore
- <sup>164</sup>Department of Medicine, Clinical Immunology and Allergy, McMaster University, Hamilton, Ontario, Canada
- <sup>165</sup>Department of Paediatrics, Prince of Wales Hospital, The Chinese University of Hong Kong, Shatin, New Territories, Hong Kong, China
- <sup>166</sup>Department of Pulmonology, Celal Bayar University, Manisa, Turkey
- <sup>167</sup>The Allergy and Asthma Institute, Islamabad, Pakistan
- <sup>168</sup>Universidad Católica de Córdoba, Universidad Nacional de Villa María, Argentina
- <sup>169</sup>Department of Otolaryngology Head and Neck Surgery, Beijing TongRen Hospital, Beijing, China
- <sup>170</sup>Respiratory and Allergic Diseases, University Clinic, Golnik, Slovenia
- <sup>171</sup>Department of Clinical Immunology, Wrocław Medical University, Wrocław, Poland
- <sup>172</sup>International Primary Care Respiratory Group IPCRG, Aberdeen, Scotland
- <sup>173</sup>European Academy of Paediatrics (EAP/UEMS-SP), Brussels, Belgium
- <sup>174</sup>Personalized Medicine, Asthma and Allergy, Humanitas Clinical and Research Center IRCCS, Rozzano, Milano, Italy
- <sup>175</sup>Department of Allergy, Al-Rashed Allergy Center, Kuwait City, Kuwait
- <sup>176</sup>International Airway Research Center, First Affiliated Hospital Guangzhou, Sun Yat-sen University, Guangzhou, China
- <sup>177</sup>Division of ENT Diseases, Department of ENT Diseases, CLINTEC, Karolinska Institutet, Karolinska University Hospital, Stockholm, Sweden
- <sup>178</sup>Research Center for Anaphylaxis (ORCA), Odense, Denmark
- <sup>179</sup>National Heart and Lung Institute, Royal Brompton Hospital & Imperial College London, UK
- <sup>180</sup>Woolcock Emphysema Centre and Sydney Local Health District, Glebe, New South Wales, Australia
- <sup>181</sup>Foundation for the Development of Medical and Biological Sciences (Fundemeb), Cartagena, Colombia
- <sup>182</sup>NOVA Medical School, CEDOC, Comprehensive Health Research Center (CHRC), Lisboa, Portugal
- <sup>183</sup>SLaai, Sociedad Latinoamericana de Alergia, Asma e Immunologia, Branquilla, Colombia
- <sup>184</sup>Equipe EPAR - IPLESP, Sorbonne Université, Paris, France
- <sup>185</sup>EUFOR, Brussels, Belgium
- <sup>186</sup>Allergy Unit, CUF Porto, Portugal
- <sup>187</sup>Center for Rhinology and Allergology, Wiesbaden, Germany
- <sup>188</sup>Sach's Children and Youth Hospital, Södersjukhuset, Stockholm, Sweden
- <sup>189</sup>Faculty of Medicine, Institute of Clinical Medicine, Clinic of Chest Diseases and Allergology, Vilnius University, Vilnius, Lithuania
- <sup>190</sup>Department of Respiratory and Sleep Medicine, Royal Prince Alfred Hospital, Sydney, Australia
- <sup>191</sup>Faculty of Medicine, Institute of Clinical Medicine, University of Oslo, Oslo, Norway
- <sup>192</sup>Department of Pediatrics, Section of Allergy and Immunology, UP-PGH, Manila, Philippines
- <sup>193</sup>Serbian Association for Asthma and COPD, Belgrade, Serbia
- <sup>194</sup>Clinical & Experimental Respiratory Immunoallergy, IDIBAPS, CIBERES, University of Barcelona, Spain
- <sup>195</sup>Alfred Health, Melbourne, Victoria, Australia
- <sup>196</sup>Department of Dermatology and Allergy Centre, Odense Research Center for Anaphylaxis (ORCA), Odense University Hospital, Odense, Denmark
- <sup>197</sup>Faculty of Medicine, Institute of Immunology, University of Coimbra, Coimbra, Portugal
- <sup>198</sup>Faculty of Medicine, ICBR - Coimbra Institute for Clinical and Biomedical Research, CIBB, University of Coimbra, Coimbra, Portugal
- <sup>199</sup>Institut de Recerca Sant Joan de Déu, Barcelona, Spain
- <sup>200</sup>Rappaport Faculty of Medicine, Technion-Israel Institute of Technology, Haifa, Israël
- <sup>201</sup>Allergy and Clinical Immunology, Imperial College London, London, UK
- <sup>202</sup>Institute of Clinical Medicine, University of Copenhagen, Copenhagen, Denmark
- <sup>203</sup>University Hospital Centre, Covilhã, Portugal
- <sup>204</sup>Faculty of Medicine, University of Coimbra, Coimbra, Portugal
- <sup>205</sup>Terveystalo Allergy Clinic, Turku, Finland
- <sup>206</sup>Otolaryngology, Beijing Institute of Otolaryngology, Beijing, China
- <sup>207</sup>ALL-MED Medical Research Institute, Wrocław, Poland

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## 1 | INTRODUCTION

Allergen immunotherapy (AIT), the gradually increasing repeated administration of high doses of allergens to allergic patients, offers

the potential for immune tolerance against reactions to the natural exposures to specific allergens. AIT may lead to the long-lasting remission of allergic symptoms and is the only disease-modifying intervention in IgE-mediated allergic respiratory diseases.



This Pocket Guide was developed by an ARIA and EAACI joint study group from a background paper of the ARIA-MASK study group and from the EAACI guidelines on allergen immunotherapy.

Bousquet J, Pfaar O, Togias A, et al. (2019). ARIA Care pathways for allergen immunotherapy. *Allergy* 2019; 74: 2087–2102.

Agache, Lau S, Akdis CA, et al. EAACI guidelines on allergen immunotherapy: house dust mite-driven allergic asthma. *Allergy*, 2019;74:855-73.

AIT is a proven therapeutic option for the treatment of allergic rhinitis, conjunctivitis, and/or asthma using sublingual (SLIT) or sub-cutaneous (SCIT) routes.

However, AIT is more expensive than symptomatic treatments for allergic diseases (excluding biologicals). It is justified (i) in patients with rhinitis otherwise uncontrolled by symptomatic treatment or (ii) as an add-on to regular asthma treatment in controlled or partially-controlled asthmatic patients sensitised to house dust mites aiming to decrease asthma exacerbations, rescue and controller medication, and to improve quality of life.

Care pathways are structured multi-disciplinary care plans detailing the key steps of patient care. They promote the translation of guideline recommendations to their application in clinical practice.

Although many international and national AIT guidelines have been produced, this is the first care pathway for AIT.

This pocket guide applies to sublingual (SLIT) and sub-cutaneous (SCIT) immunotherapy for allergic rhinitis.

It has been revised by members from 65 countries (Figure 1).

## 2 | ALLERGENS TO BE ADMINISTERED

The decision to prescribe AIT should be based on relevant symptoms during allergen exposure, demonstration of sensitisation to the relevant allergens, and availability of good-quality extracts with proven efficacy and safety.

Some allergen extracts are approved for marketing in the EU (list in annex) with some others also approved by national health agencies.

For certain products, efficacy and safety have been demonstrated in appropriate clinical studies on adults and children. The extrapolation to untested products, allergens or a different population from the one evaluated in the trial is not appropriate and not in line with current guidelines as there is no class-effect in AIT.

Both monosensitised and polysensitised patients can be treated. However, in the latter case, the most clinically relevant allergen(s) should be used when symptoms are clearly present with allergen source exposure and when allergy tests confirm clinical findings.

## 3 | STRATIFICATION OF ALLERGIC PATIENTS

Precision medicine aims at the customisation of healthcare, tailored to the characteristics of each individual patient. The stratification of patients into subpopulations is the basis of clinical decision making (Figure 2).

In allergic diseases, patient stratification is required to:

- Propose the appropriate pharmacotherapy.
- Identify the most suitable candidates for AIT.
- Reduce the amount of time and resources needed to match the right patient to an optimal care management programme.
- Optimise costs as expensive therapeutic interventions are not necessary or suitable for all patients.

Patient stratification may also help to improve the patient's engagement.

### 3.1 | Precision medicine in the indication of AIT

1. Precise diagnosis with history, skin prick tests and/or specific IgE and, if applicable, component-resolved in vitro testing. In some cases, where the above-mentioned diagnostic tools do not allow for precise diagnosis, allergen provocation testing (nasal, ocular and, in some cases, bronchial) may be needed.
2. Proven indications: Allergic rhinitis, conjunctivitis and/or asthma.
3. Symptoms predominantly induced by the relevant allergen exposure.
4. Patient stratification:
  - Poor control of nasal or ocular symptoms despite optimal medications according to guidelines with documented adherence to treatment.
  - Exceptions to requiring optimum symptomatic treatment prior to considering AIT include unacceptable side effects of the medications.
  - Allergic asthma fully controlled under background asthma medication (see EAACI HDM-AIT GL)
  - However, for partially controlled asthma, HDM-AIT may facilitate achieving asthma control (see EAACI HDM-AIT GL)
5. Good clinical documentation of efficacy and safety for the AIT product with relevant trials.
6. The patient's (and caregiver's) views represent an essential component.

### 3.2 | Biomarkers

There are currently no in vivo or in vitro biomarkers validated for monitoring the efficacy of AIT although several potential candidates are currently being investigated.

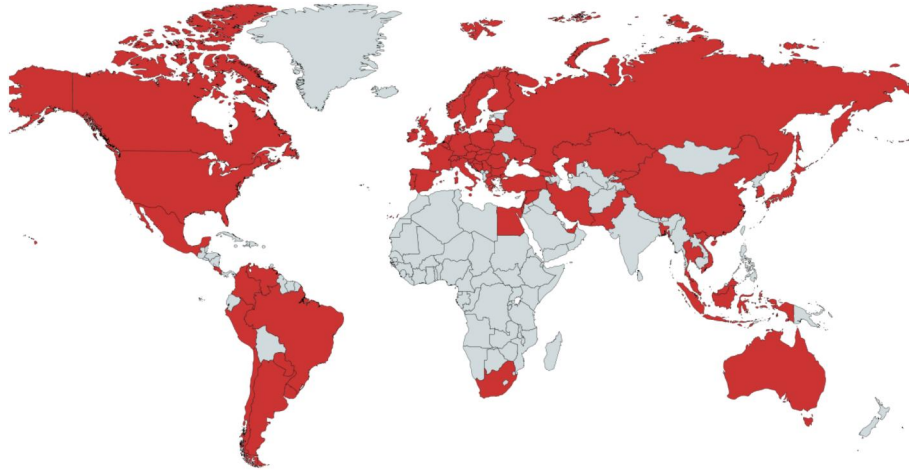


FIGURE 1 Countries with Pocket Guide members

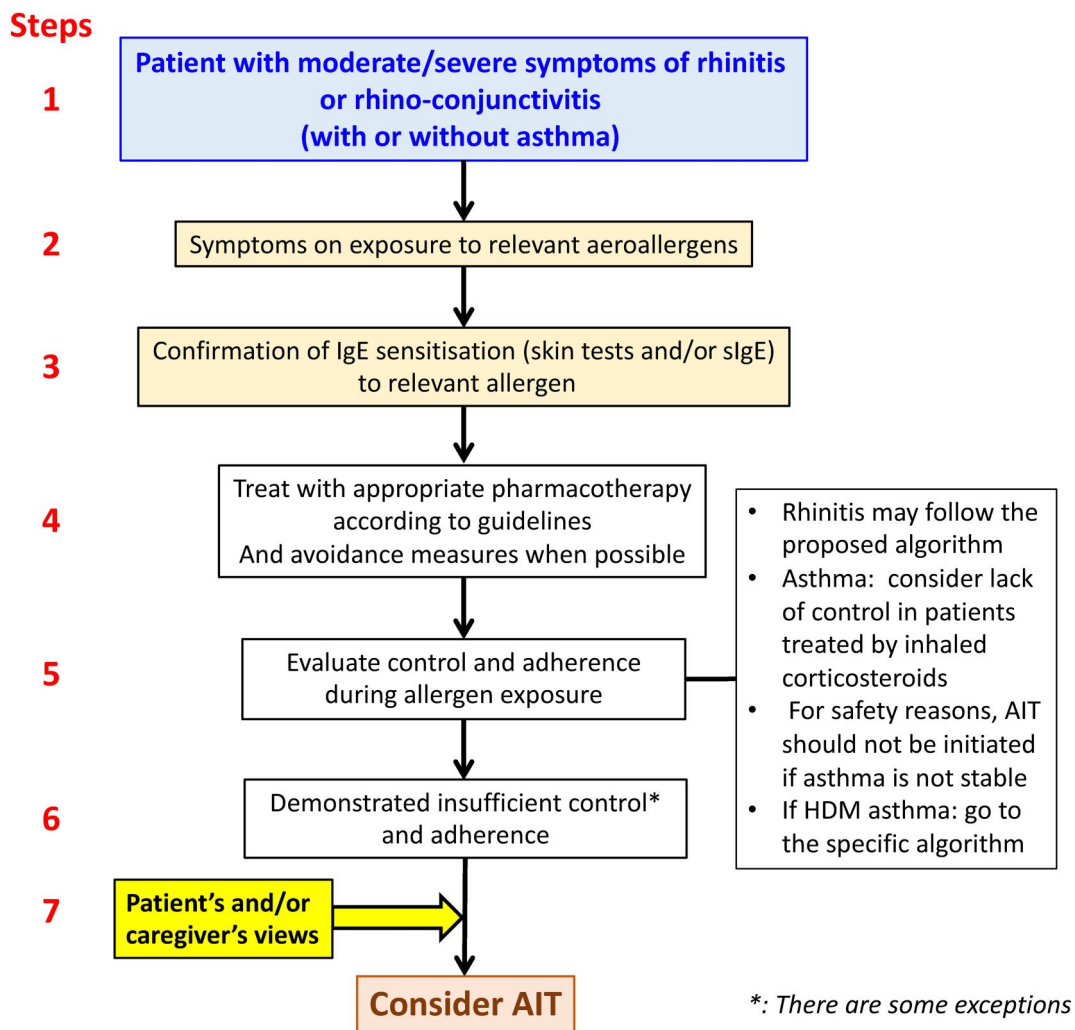


FIGURE 2 Proposed Flow of Precision Medicine approach in allergic diseases. \*examples of exceptions: Thunderstorm-induced asthma, patient with moderate rhinitis and severe asthma during pollen season

## 4 | mHEALTH

Apps can be used:

- To acquire real-world evidence to confirm the efficacy of AIT in situations where randomised controlled trials are difficult to perform.
- To assess air quality index including pollen exposure and air pollution.
- By physicians and patients for stratification of patients and follow-up.

## 5 | RHINITIS (WITH OR WITHOUT CONJUNCTIVITIS) IN ADOLESCENTS AND ADULTS

The selection of pharmacotherapy and AIT for patients with AR and/or allergic conjunctivitis may be better supported by evidence algorithms to aid patients and healthcare professionals jointly determine the treatment and its step-up or step-down strategy depending on rhinitis control (shared decision-making).

A simple algorithm is proposed as an aid for physicians to determine the treatment of their patients (Figure 3).

### 5.1 | Treatment algorithm using visual analogue scale (VAS)

In the case of remaining ocular symptoms, add intra-ocular treatment.

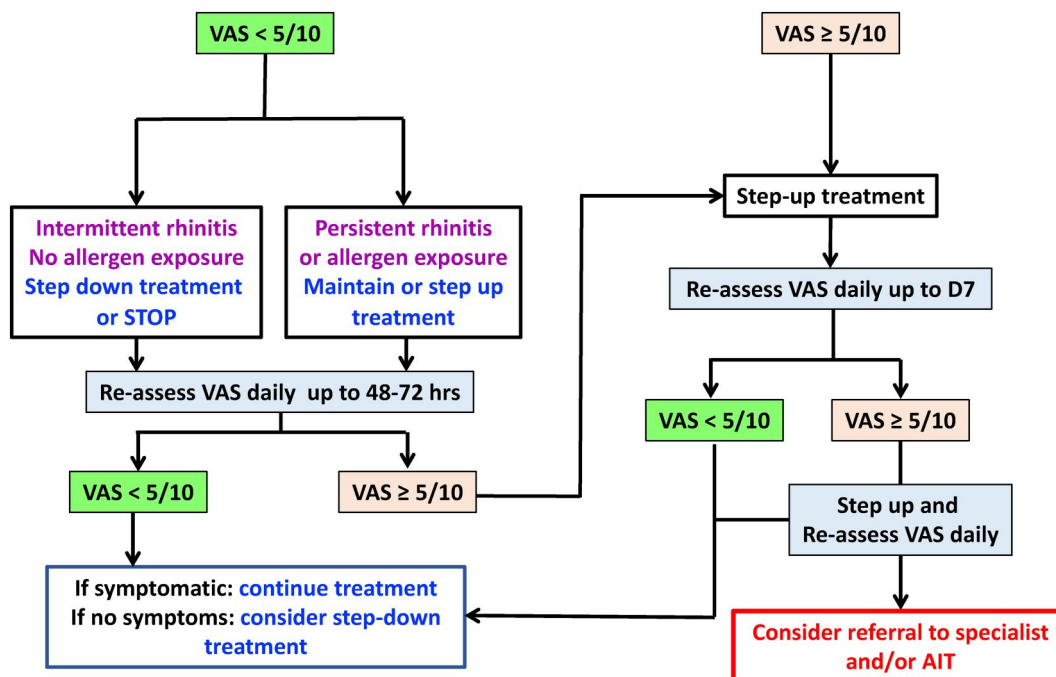


FIGURE 3 Treatment algorithm using visual analogue scale (VAS) for adolescents and adults AIT, allergen immunotherapy; VAS, visual analogue scale.

## 6 | RHINITIS (WITH OR WITHOUT CONJUNCTIVITIS) IN CHILDREN

AIT is effective, has long-term beneficial effects after cessation, and may delay or prevent the onset of asthma. AIT can be initiated in children with moderate/severe rhinitis that is not controlled by appropriate medications according to guidelines.

## 7 | ASTHMA

An algorithm for HDM-driven allergic asthma diagnosis and management is proposed by the EAACI guidelines.

For patients with concomitant allergic rhinitis and sensitised to house dust mite—with persisting asthma symptoms despite low-moderate dose of inhaled corticosteroids—SLIT can be considered, provided FEV1 is >70% predicted.

House dust mite SLIT should initially be considered as an add-on therapy to controller treatment, and reduction in asthma controllers should be performed gradually under the supervision of a physician.

Immunotherapy is not indicated for the treatment of acute exacerbations, and patients must be informed of the need to seek medical attention immediately if their asthma deteriorates suddenly (Figure 4).

## 8 | MULTIMORBIDITY

One strength of AIT is that it has the potential to control all allergic diseases related to a specific allergen, including rhinitis, conjunctivitis and asthma.



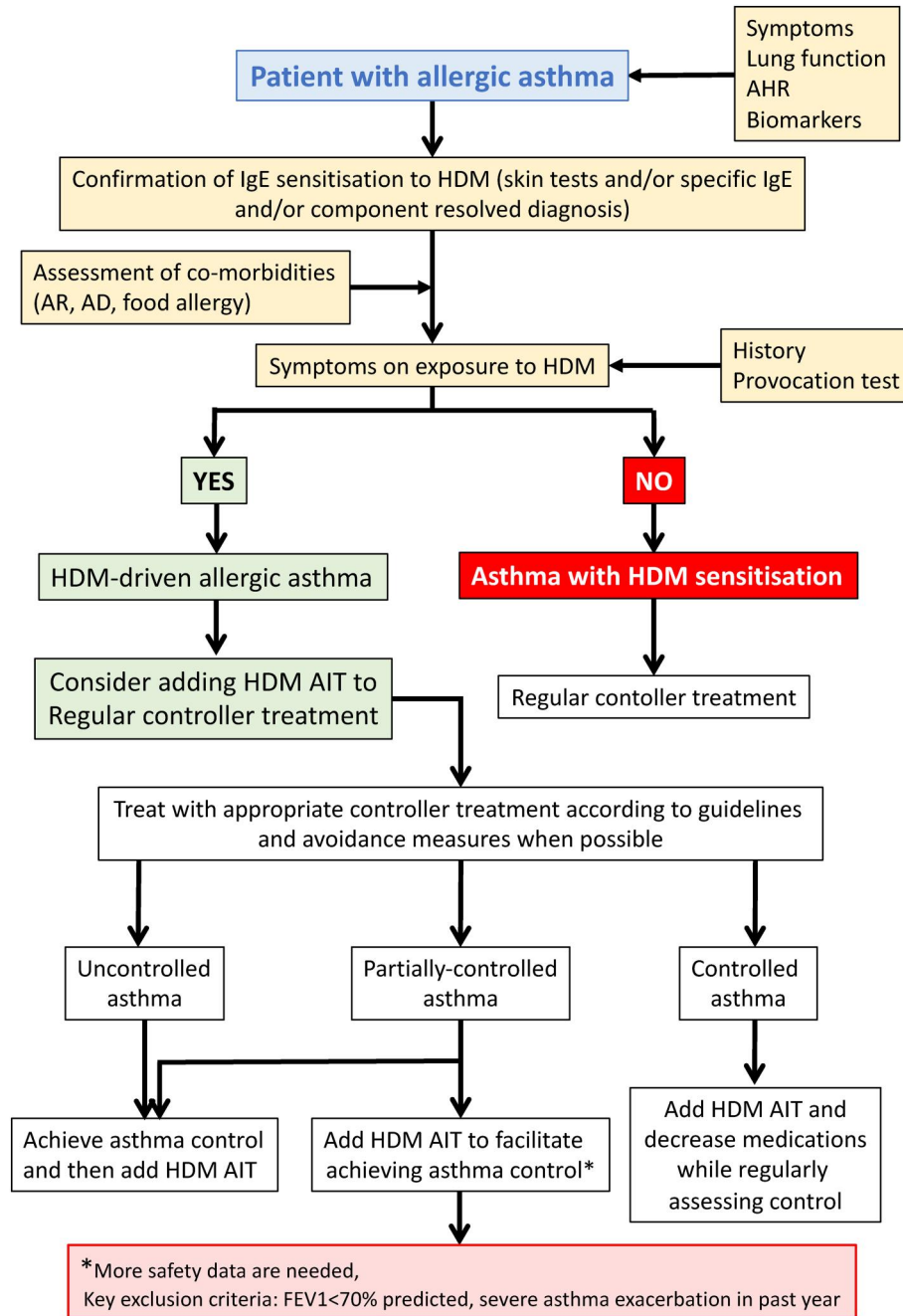


FIGURE 4 Algorithm for AIT in asthma

## 9 | SAFETY

### 9.1 | Subcutaneous immunotherapy (SCIT)

**Local reactions:** A typical reaction is redness and swelling at the injection site immediately or several hours after the injection. Sometimes, sneezing, nasal congestion or hives can occur.

**Systemic reactions:** Serious reactions to injections are very rare and require immediate medical attention. Symptoms of an anaphylactic reaction can include swelling in the throat, wheezing or tightness in the chest, nausea and dizziness. The most serious reactions

develop within 30 min after the injection, and patients are advised to wait in their doctor's surgery for at least 30 min after an injection. Severe bronchospasm can also occur, especially in patients where asthma is not controlled.

### 9.2 | Sublingual immunotherapy (SLIT)

Allergen drops or tablets have a more favourable safety profile than injections. The initial dose should be performed in the doctor's surgery, and patients are advised to remain in the surgery for at least 30 min

after administration. Thereafter, SLIT can be administered at home once the first dose has been given under the supervision of a physician.

Allergic reactions: The majority of patients will experience mild local reactions of the oropharyngeal passage. This is usually controlled by pre-dosing with an antihistamine 30 min before the administration of SLIT. Sometimes, sneezing, nasal congestion or hives can occur. Anaphylaxis is rarely described.

In some countries, SLIT tablets include a warning about possible severe allergic reactions, and adrenaline auto-injectors are routinely recommended. This is not the case in Europe.

## CONFLICT OF INTEREST

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GS reports personal fees from ALK, and leads on the BSACI Rhinitis Guidelines and lead for EUFOREA on Allergic Rhinitis.

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DW reports other from Optinose, ALK, Sanofi; past Co-Chair of the Joint Task Force on Practice Parameters of the AAAAI and ACAAI. Second author of a recently published practice parameter on Rhinitis.

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MZ reports personal fees from Takeda.

TZ reports and Organizational affiliations: Committee member: WHO-Initiative "Allergic Rhinitis and Its Impact on Asthma" (ARIA). Member of the Board: German Society for Allergy and Clinical

Immunology (DGAKI). Head: European Centre for Allergy Research Foundation (ECARF). Secretary General: Global Allergy and Asthma European Network (GA<sup>2</sup>LEN). Member: Committee on Allergy Diagnosis and Molecular Allergology, World Allergy Organization (WAO).

#### ORCID

Jean Bousquet  <https://orcid.org/0000-0002-4061-4766>

Victoria Cardona  <https://orcid.org/0000-0003-2197-9767>

Ralph Mösges  <https://orcid.org/0000-0002-1928-810X>

Dermot Ryan  <https://orcid.org/0000-0002-4115-7376>

Manuel Soto-Quiros  <https://orcid.org/0000-0003-3425-3463>

Isabel Skypala  <https://orcid.org/0000-0003-3629-4293>

Mihaela Zidarn  <https://orcid.org/0000-0003-0515-5207>

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