

Briefing Note:

Digital Adherence Technologies for Tuberculosis Programs

1. Purpose

This document has been developed to provide guidance to National TB Programs and Global Fund Principal Recipients or implementers on planning, budgeting, and implementation considerations to take into account during the selection of TB Digital Adherence Technologies (DATs).

2. Use of Digital Adherence Technologies in Tuberculosis Programs

In the successful fight against TB, it is important for healthcare providers to follow and support the patient journey as well as identify and prioritize people who require more support in completing their TB treatment.

Digital Adherence Technologies (DATs) are digital tools that utilize mobile phone, computer, web-based and/or electronic sensor technology to support the capture of daily detailed patient-specific adherence information.

These technologies can help to support people affected by TB with their treatment in a modern and effective way. They help empower TB affected individuals and their families to take their daily medication at a time and place that suits them best, rather than relying on the traditional approach for monitoring adherence through directly observed treatment (DOT).

DATs offer the opportunity for healthcare providers to follow and support the person with TB during treatment and identify people who need additional assistance.

3. An Overview of the Digital Adherence Technologies

3.1 Medication Sleeve / Label

The <u>medication sleeve/label</u>, also called 99DOTS, use customized packaging such as a printed sleeves or labels that fit Fixed Dose Combination (FDC) medication.





The person on TB treatment reports medication intake daily either by calling a toll-free phone number or sending a toll-free SMS message using a code found on the customized packaging. Any type of mobile phone can be utilized to submit the code to the adherence platform.

The medication sleeve/label does not have a direct procurement mechanism, but requires a tailor-made, in-country approach. For further information, <u>please consult the following web page.</u>

3.2 Smart Pill Box

With the use of a medication container, a battery powered sensor and a mobile data connection, the <u>smart pill box</u> automatically logs medication intake by sending a signal each time the person opens the box to take their medication.



Features:

- Battery that lasts up to 6 months before it requires a recharge.
- Global mobile data subscription for 36 months (when procured through the Global Drug Facility).
- Various container sizes available to store and organize up to a month's supply of medication.
- LED and speaker to enable visual/audible dose reminders.

Procurement for the Smart Pill Box can be done through <u>the Global Drug Facility</u>, or directly through <u>Wisepill</u> (the manufacturers).

3.3 Video Supported Treatment

<u>Video Supported Treatment (VST)</u> allows the person on TB treatment to video record and submit their medication intake, which the healthcare provider can review at a later stage.

Patients are guided through a secured mobile application to record videos of themselves taking their daily medication. The video is then uploaded





to a secure server that can be accessed by the healthcare provider to review the doses taken.

Procurement of VST is dependent on the application used. There are multiple VST application options currently available. VST application options include:

- <u>SureAdhere/Everwell hub</u>: Used in several <u>ASCENT project</u> countries. The app can be procured with the guidance of <u>SureAdhere</u>.
- <u>TBVOT.MD</u>: Used in Moldova and replicated for use in other countries in the Eastern Europe/Central Asia region. The app can be procured from the app developers – QSystems.
- <u>Adhere2Tx-TB</u>: Used in Georgia and replicated for use in Azerbaijan, Armenia, and Kazakhstan. The app can be procured from the app developers <u>Leavingstone</u>.

3.4 Adherence Platform

The above-described technologies need to be linked to an online digital adherence platform, where medication intake data is automatically collected in a structured and usable way for the healthcare providers.

Healthcare providers can access their patients' daily adherence information through the adherence platform, which helps them in shaping the most suitable treatment response for each individual person.

Further information about the adherence platform can be found here.



4. Budgeting

Budgeting for digital adherence technologies differs per technology, and is influenced by country specific factors, such as data and SMS costs in country; number of people registered on the program; and costs for additional in-country infrastructure.

Costs for implementation are split into two categories. These include:

- Procurement costs (for example the technology to report adherence with; and device for healthcare providers to view their patient's adherence information daily).
- Contractual costs (such as monthly costs for the adherence platform and cloud hosting).

Generally, the cost per person on TB treatment decreases as the DAT roll-out increases. The project therefore becomes more cost effective when more people are enrolled, as cost can be spread out across all people using DATs, and DATs can be reused for new enrollments.

Costing estimates for each technology are provided below, with a detailed costing breakdown per technology in the annexes.

4.1 Medication Label

The cost estimates of the medication label are dependent on number of people enrolled on treatment; the enrollment duration; supportive infrastructure costs; and whether additional devices, data, and airtime are provided to the healthcare facilities.

For a detailed breakdown for the total cost of implementation for the medication label, please consult annex 1 and annex 2.

	Upper cost range	Lower cost range
Up to 2000 people enrolled	USD 57 per person	USD 41 per person
Up to 5000 people enrolled	USD 34 per person	USD 24 per person

4.2 Smart Pill Box

The cost estimates of the smart pill box are dependent on number of people enrolled on treatment; the enrollment duration; and whether additional devices, data, and airtime are provided to the healthcare facilities.

For a detailed breakdown for the total cost of implementation for the smart pill box, please consult annex 3 and annex 4.

	Upper cost range	Lower cost range
Up to 2000 people enrolled	USD 87 per person	USD 55 per person
Up to 5000 people enrolled	USD 67 per person	USD 40 per person

4.3 Video Supported Treatment (VST)

The cost estimates of video supported treatment (VST) are dependent on number of people enrolled on treatment; the enrollment duration; whether a smart phone and monthly data for people on treatment are provided; and whether additional devices, monthly data, and airtime to the healthcare facilities is provided.

For a detailed breakdown for the total cost of implementation for VST, please consult <u>annex 5</u> and <u>annex 6</u>.

	Upper cost range	Lower cost range
Up to 2000 people enrolled	USD 338 per person	USD 31 per person
Up to 5000 people enrolled	USD 318 per person	USD 17 per person

5. Policy Recommendations

- 1. Drug-resistant TB: The WHO recommends the use of digital adherence technologies, including the smart pill box and video supported treatment in their <u>WHO consolidated</u> guidelines on drug-resistant tuberculosis treatment.
- 2. Drug-sensitive TB: The WHO recommends that digital adherence technologies may be offered to patients as a complementary tool during TB treatment in their <u>guidelines for treatment of drug-susceptible tuberculosis and patient care.</u>
- 3. Tuberculosis preventive treatment: According to the <u>WHO consolidated guidelines on tuberculosis</u> the WHO states that digital adherence technologies are an important area in adherence improvement which requires further research.

6. Guidance and Support

While continuing the evaluation and research of DATs in practice, the <u>Global DAT Task Force</u> offers technical support for optimal introduction and scale-up of DATs for national TB programmes.

Should you require guidance for DAT funding proposal development, the introduction and/or scale-up of DAT interventions, research, or short- and long- term budget development and planning of resources, please <u>contact the Global DAT Task Force.</u>



Image: Global DAT Task Force Partner Organizations

7. Resources

- 1. <u>Handbook for the use of Digital Technologies to Support Tuberculosis Adherence</u>. World Health Organization.
- 2. A Quick Guide to Video Supported Treatment of Tuberculosis. World Health Organization.
- 3. <u>An overview, considerations, and implementation requirements of digital adherence technologies.</u> The Global DAT Task Force.
- 4. <u>Guidance for implementation a stepwise approach</u>. The Global DAT Task Force.
- 5. <u>GDF Technical Information Note Smart Medicines Container Kit</u>. StopTBPartnership and the Global Drug Facility.
- 6. <u>Total Cost of Ownership Tool to generate DAT implementation cost estimates</u>. The ASCENT Project.
- 7. <u>Fighting Pandemics and Building a Healthier and More Equitable World: The Global Fund Strategy (2023-2028).</u> The Global Fund.

Annex 1: Budgeting for the Medication Labels: 2000 Patients Enrolled Per Year

	1 year project Up to 2000 patient enrollments p/year	2-year project Up to 2000 patient enrollments p/year	3-year project Up to 2000 patient enrollments p/year
Procurement of medication labels for 2000 patients per year	USD 5 000	USD 10 000	USD 15 000
Adherence platform* once off setup and training costs (up to 2000 patients)	USD 32 000	USD 32 000	USD 32 000
Adherence platform* contractual costs @ USD 4000 per month	USD 48 000	USD 96 000	USD 144 000
Infrastructure costs for SMS short code line rental or toll-free number line rental @ USD 90 per month	USD 1 080	USD 2 160	USD 3 240
Incoming and outgoing SMS costs from the patient	USD 11 200	USD 22 400	USD 33 600
Yearly renewable telecom infrastructure costs @ USD 7000 per year**	USD 7 000	USD 14 000	USD 21 000
Tablets for 20 healthcare facilities to access adherence platform (1 x tablet per facility @ USD 250 per device) ***	USD 5 000	USD 5 000	USD 5 000
Mobile data costs & airtime for 20 x tablets for facilities @ USD 16 per month ***	USD 3 840	USD 7 680	USD 11 520

Total cost for implementation all	USD 113 120	USD 189 240	USD 265 360
inclusive			
**Total cost for implementation excl.	USD 106 120	USD 175 240	USD 244 360
yearly renewable telecom infrastructure			
costs			
***Total cost for implementation excl.	USD 104 280	USD 176 560	USD 248 840
tablets and data for facilities			

Total cost per patient all inclusive	IISD 56 56 per natient	USD 47.31 per patient	USD 44.23 per patient
		OSD 47.51 per patient	OSD 44.25 per patient
**Total cost per patient excl. yearly	USD 53.06 per patient	USD 43.82 per patient	USD 40.73 per patient
renewable telecom infrastructure costs			
***Total cost per patient excl. tablets and	USD 52.14 per patient	USD 44.14 per patient	USD 41.47 per patient
data for facilities			

^{*} The *adherence platform* costs are based on pricing received from Everwell Health Solutions, and may vary if a different software developer for the adherence platform is utilized.

^{**} Yearly renewable telecom infrastructure costs for a toll-free line, SMS shortcode or USSD code are only applicable in some countries. It is advised to find out in your country whether there are yearly renewable costs associated with a toll-free line, SMS shortcode or USSD code for patients to report their adherence to. If there are no yearly renewable costs, this line item can be removed.

*** Tablets and mobile data for facilities can be excluded from the total cost for implementation if each implementing healthcare facility already has daily access to a tablet/smartphone, laptop, or desktop with internet access to review adherence data on the adherence platform. It is also important to note that costs for a tablet, data and airtime vary drastically per country. Therefore, an average of USD 250 per tablet and USD 16 per month for data & airtime has been applied. This line item may therefore be adjusted if there is a large difference between these average costs provided, and the costs within your country.

Annex 2: Budgeting for the Medication Labels: 5000 Patients Enrolled Per Year

	1 year project Up to 5000 patient enrollments p/year	2-year project Up to 5000 patient enrollments p/year	3-year project Up to 5000 patient enrollments p/year
Procurement of medication labels for 5000 patients per year	USD 12 500	USD 25 000	USD 37 500
Adherence platform* once off setup and training costs (up to 5000 patients)	USD 40 000	USD 40 000	USD 40 000
Adherence platform* contractual costs @ USD 5000 per month	USD 60 000	USD 120 000	USD 180 000
Infrastructure costs for SMS short code line rental or toll-free number line rental @ USD 90 per month	USD 1 080	USD 2 160	USD 3 240
Incoming and outgoing SMS costs from the patient	USD 28 000	USD 56 000	USD 84 000
Yearly renewable telecom infrastructure costs @ USD 7000 per year**	USD 7 000	USD 14 000	USD 21 000
Tablets for 50 healthcare facilities to access adherence platform (1 x tablet per facility @ USD 250 per device) ***	USD 12 500	USD 12 500	USD 12 500
Mobile data costs & airtime for 50 x tablets for facilities @ USD 16 per month ***	USD 9 600	USD 19 200	USD 28 800

Total cost for implementation all	USD 170 680	USD 288 860	USD 407 040
inclusive			
**Total cost for implementation excl. yearly renewable telecom infrastructure	USD 163 680	USD 274 860	USD 386 040
costs			
***Total cost for implementation	USD 148 580	USD 257 160	USD 365 740
excluding tablets and data for facilities			

Total cost per patient all inclusive	USD 34.14 per patient	USD 28.89 per patient	USD 27.14 per patient
• •		•	•
**Total cost per patient excl. yearly	USD 32.74 per patient	USD 27.49 per patient	USD 25.74 per patient
renewable telecom infrastructure costs			
***Total cost per patient excl. tablets and	USD 29.72 per patient	USD 25.72 per patient	USD 24.38 per patient
data for facilities			

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^{**} Yearly renewable telecom infrastructure costs for a toll-free line, SMS shortcode or USSD code are only applicable in some countries. It is advised to find out in your country whether there are yearly renewable costs associated with a toll-free line, SMS shortcode or USSD code for patients to report their adherence to. If there are no yearly renewable costs, this line item can be removed.

*** Tablets and mobile data for facilities can be excluded from the total cost for implementation if each implementing healthcare facility already has daily access to a tablet/smartphone, laptop, or desktop with internet access to review adherence data on the adherence platform. It is also important to note that costs for a tablet, data and airtime vary drastically per country. Therefore, an average of USD 250 per tablet and USD 16 per month for data & airtime has been applied. This line item may therefore be adjusted if there is a large difference between these average costs provided, and the costs within your country.

Annex 3: Budgeting for the Smart Pill Box: 2000 Patients Enrolled Per Year

	1 year project Up to 2000 patient enrollments p/year	2-year project Up to 2000 patient enrollments p/year	3-year project Up to 2000 patient enrollments p/year
Procurement of smart pill boxes* for 2000 patients per year	USD 85 250	USD 135 000 *	USD 152 750 *
Adherence platform** once off setup and training costs (up to 2000 patients)	USD 32 000	USD 32 000	USD 32 000
Adherence platform** contractual costs @ USD 4000 per month	USD 48 000	USD 96 000	USD 144 000
Tablets for 20 healthcare facilities to access adherence platform (1 x tablet per facility @ USD 250 per device) ***	USD 5 000	USD 5 000	USD 5 000
Mobile data costs & airtime for 20 x tablets for facilities @ USD 16 per month ***	USD 3 840	USD 7 680	USD 11 520
Total cost for implementation all inclusive	USD 174 090	USD 275 680	USD 345 270
***Total cost for implementation excluding tablets and data for facilities	USD 165 250	USD 263 000	USD 328 750
Total cost per patient all inclusive	USD 87.05 per patient	USD 68.92 per patient	USD 57.55 per patient
***Total cost per patient excl. tablets and	USD 82.63 per patient	USD 65.75 per patient	USD 54.79 per patient

data for facilities

^{*} Costs for the *smart pill box* are based on procurement of a *smart pill box kit* (medication container; module with battery; battery charger) for year 1 of a project. The reuse of the module and battery charger is assumed if the project continues for 2 or 3 years. There is provision in the above budget projections for the procurement of additional plastic medication containers only in a 2- or 3-year project.

^{**} The *adherence platform* costs are based on pricing received from Everwell Health Solutions, and may vary if a different software developer for the adherence platform is utilized.

^{***} Tablets and mobile data for facilities can be excluded from the total cost for implementation if each implementing healthcare facility already has daily access to a tablet/smartphone, laptop, or desktop with internet access to review adherence data on the adherence platform. It is also important to note that costs for a tablet, data and airtime vary drastically per country. Therefore, an average of USD 250 per tablet and USD 16 per month for data & airtime has been applied. This line item may therefore be adjusted if there is a large difference between these average costs provided, and the costs within your country.

Annex 4: Budgeting for the Smart Pill Box: 5000 Patients Enrolled Per Year

	1 year project Up to 5000 patient enrollments p/year	2-year project Up to 5000 patient enrollments p/year	3-year project Up to 5000 patient enrollments p/year
Procurement of smart pill boxes* for	USD 213 125	USD 337 500 *	USD 381 875 *
5000 patients per year			
Adherence platform** once off setup	USD 40 000	USD 40 000	USD 40 000
and training costs (up to 5000 patients)			
Adherence platform** contractual costs	USD 60 000	USD 120 000	USD 180 000
@ USD 5000 per month			
Tablets for 50 healthcare facilities to	USD 12 500	USD 12 500	USD 12 500
access adherence platform (1 x tablet per			
facility @ USD 250 per device) ***			
Mobile data costs & airtime for 50 x tablets	USD 9 600	USD 19 200	USD 28 800
for facilities @ USD 16 per month ***			

Total cost for implementation all inclusive	USD 335 225	USD 529 200	USD 643 175
***Total cost for implementation excluding tablets and data for facilities		USD 497 500	USD 601 875

Total cost per patient all inclusive	USD 67.05 per patient	USD 52.92 per patient	USD 42.88 per patient
***Total cost per patient excl. tablets and	USD 62.63 per patient	USD 49.75 per patient	USD 40.13 per patient
data for facilities			

^{*} Costs for the *smart pill box* are based on procurement of a *smart pill box kit* (medication container; module with battery; battery charger) for year 1 of a project. The reuse of the module and battery charger is assumed if the project continues for 2 or 3 years. There is provision in the above budget projections for the procurement of additional plastic medication containers only in a 2- or 3-year project.

^{**} The *adherence platform* costs are based on pricing received from Everwell Health Solutions, and may vary if a different software developer for the adherence platform is utilized.

^{***} Tablets and mobile data for facilities can be excluded from the total cost for implementation if each implementing healthcare facility already has daily access to a tablet/smartphone, laptop, or desktop with internet access to review adherence data on the adherence platform. It is also important to note that costs for a tablet, data and airtime vary drastically per country. Therefore, an average of USD 250 per tablet and USD 16 per month for data & airtime has been applied. This line item may therefore be adjusted if there is a large difference between these average costs provided, and the costs within your country.

Annex 5: Budgeting for the Video Supported Treatment (VST): 2000 Patients Enrolled Per Year

	1 year project Up to 2000 patient enrollments p/year	2-year project Up to 2000 patient enrollments p/year	3-year project Up to 2000 patient enrollments p/year
Adherence platform* once off setup and training costs (up to 2000 patients)	USD 32 000	USD 32 000	USD 32 000
Adherence platform* contractual costs @ USD 4000 per month	USD 48 000	USD 96 000	USD 144 000
Adherence platform* contractual costs for patients on VST @ USD 2 per patient	USD 4 000	USD 8 000	USD 12 000
Data costs** for 2000 x patients to submit video recordings @ USD 16 per month per patient	USD 384 000	USD 768 000	USD 1 152 000
Procurement of smart phones for 2000 patients @ USD 100 per phone **	USD 200 000	USD 240 000	USD 260 000
Tablets for 20 healthcare facilities to access adherence platform (1 x tablet per facility @ USD 250 per device) ***	USD 5 000	USD 5 000	USD 5 000
Mobile data costs & airtime for 20 x tablets for facilities @ USD 16 per month ***	USD 3 840	USD 7 680	USD 11 520

Total cost for implementation all inclusive	USD 676 840	USD 1 156 680	USD 1 616 520
**Total cost for implementation excl.	USD 92 840	USD 148 680	USD 204 520
smart phones and data for patients			
***Total cost for implementation excl.	USD 668 000	USD 1 144 000	USD 1 600 000
tablets and data for facilities			
****Total cost for implementation excl.	USD 84 000	USD 136 000	USD 188 000
smart phones and data for patients; and			
tablets and data for facilities			

Total cost per patient all inclusive	USD 338.42 per	USD 289.17 per	USD 269.42 per
	patient	patient	patient
**Total cost per patient excl. smart phones	USD 46.42 per patient	USD 37.17 per patient	USD 34.09 per patient
for patients			
***Total cost per patient excl. tablets and	USD 334.00 per patient	USD 286 per patient	USD 266.67 per patient
data for facilities			
****Total cost per patient excl. smart	USD 42.00 per patient	USD 34 per patient	USD 31.33 per patient
phones and data for patients; and tablets			
and data for facilities			

^{*} The *adherence platform* costs are based on pricing received from Everwell Health Solutions, and may vary if a different software developer for the patient app to record daily medication intake and adherence platform is utilized.

** Smart phone procurement and data costs for the patients can be excluded from the total cost for implementation if TB programme is relying on patients to utilize their own smart phone and has access to Wi-Fi or internet connection daily. It is also important to note that costs for a smart phone and data vary drastically per country. Therefore, an average of USD 100 per smart phone and USD 16 per month for data has been applied. This line item may therefore be adjusted if there is a large difference between these average costs provided, and the costs within your country.

A reuse rate is assumed for the smart phones for patients if the project continues beyond 1 year. To make provision for lost or damaged phones a 20% overstocking is applied for a 2-year project, and a 30% overstocking is applied to a 3-year project.

*** Tablets and mobile data for facilities can be excluded from the total cost for implementation if each implementing healthcare facility already has daily access to a tablet, laptop, or desktop with internet access to review adherence data on the adherence platform. It is also important to note that costs for a tablet, data and airtime vary drastically per country. Therefore, an average of USD 250 per tablet and USD 16 per month for data & airtime has been applied. This line item may therefore be adjusted if there is a large difference between these average costs provided, and the costs within your country.

**** If the national TB programme is not providing smart phones and data to patients, and tablets and data to the healthcare facility, these line items can be removed to calculate the total cost for implementation.

Annex 6: Budgeting for the Video Supported Treatment (VST): 5000 Patients Enrolled Per Year

	1 year project Up to 5000 patient enrollments p/year	2-year project Up to 5000 patient enrollments p/year	3-year project Up to 5000 patient enrollments p/year
Adherence platform* once off setup and training costs (up to 5000 patients)	USD 40 000	USD 40 000	USD 40 000
Adherence platform* contractual costs @ USD 5000 per month	USD 60 000	USD 120 000	USD 180 000
Adherence platform* contractual costs for patients on VST @ USD 2 per patient	USD 10 000	USD 20 000	USD 30 000
Data costs** for 5000 x patients to submit video recordings @ USD 16 per month per patient	USD 960 000	USD 1 920 000	USD 2 880 000
Procurement of smart phones for 5000 patients @ USD 100 per phone **	USD 500 000	USD 600 000	USD 650 000
Tablets for 50 healthcare facilities to access adherence platform (1 x tablet per facility @ USD 250 per device) ***	USD 12 500	USD 12 500	USD 12 500
Mobile data costs & airtime for 50 x tablets for facilities @ USD 16 per month ***	USD 9 600	USD 19 200	USD 28 800

Total cost for implementation all	USD 1 592 100	USD 2 731 700	USD 3 821 300
inclusive			
**Total cost for implementation excl.	USD 132 100	USD 211 700	USD 291 300
smart phones and data for patients			
***Total cost for implementation excl.	USD 1 570 000	USD 2 700 000	USD 3 780 000
tablets and data for facilities			
****Total cost for implementation excl.	USD 110 000	USD 180 000	USD 250 000
smart phones and data for patients; and			
tablets and data for facilities			

Total cost per patient all inclusive	USD 318.42 per	USD 273.17 per	USD 254.75 per
	patient	patient	patient
**Total cost per patient excl. smart phones	USD 26.42 per patient	USD 21.17 per patient	USD 19.42 per patient
and data for patients			
***Total cost per patient excl. tablets and	USD 314.00 per patient	USD 270 per patient	USD 252.00 per patient
data for facilities			
****Total cost per patient excl. smart	USD 22.00 per patient	USD 18.00 per patient	USD 16.67 per patient
phones and data for patients; and tablets			
and data for facilities			

^{*} The *adherence platform* costs are based on pricing received from Everwell Health Solutions, and may vary if a different software developer for the patient app to record daily medication intake and adherence platform is utilized.

** Smart phone procurement and data costs for the patients can be excluded from the total cost for implementation if TB programme is relying on patients to utilize their own smart phone and has access to Wi-Fi or internet connection daily. It is also important to note that costs for a smart phone and data vary drastically per country. Therefore, an average of USD 100 per smart phone and USD 16 per month for data has been applied. This line item may therefore be adjusted if there is a large difference between these average costs provided, and the costs within your country.

*** Tablets and mobile data for facilities can be excluded from the total cost for implementation if each implementing healthcare facility already has daily access to a tablet, laptop, or desktop with internet access to review adherence data on the adherence platform. It is also important to note that costs for a tablet, data and airtime vary drastically per country. Therefore, an average of USD 250 per tablet and USD 16 per month for data & airtime has been applied. This line item may therefore be adjusted if there is a large difference between these average costs provided, and the costs within your country.

**** If the national TB programme is not providing smart phones and data to patients, and tablets and data to the healthcare facility, these line items can be removed to calculate the total cost for implementation.